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Contents

Federal Register

Vol. 87, No. 153

Wednesday, August 10, 2022

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

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

CFR PARTS AFFECTED IN THIS ISSUE

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

3 CFR

Proclamations:

10428.....48601

25 CFR

Proposed Rules:

502.....48613
556.....48613
558.....48613
585.....48615

40 CFR

60.....48603
63.....48603

42 CFR

410.....48609
412.....48780
413.....48780
414 (2 documents) 48609
482.....48780
485.....48780
495.....48780

48 CFR

Ch. 1 (2 documents) 49502, 49503
4.....49502
13.....49502
17.....49502
23.....49502
51.....49502
52.....49502

50 CFR

622.....48610
679.....48611

Proposed Rules:

648.....48617

Federal Register
Vol. 87, No. 153
Wednesday, August 10, 2022

Presidential Documents

Title 3—

The President

Proclamation 10428 of August 5, 2022

National Health Center Week, 2022

By the President of the United States of America

A Proclamation

Over half a century ago, President Lyndon B. Johnson piloted a program to deliver affordable primary health care to Americans who needed it most. He helped establish community health centers in underserved areas, making medical services accessible to people irrespective of their age, geography, or economic status. President Johnson's philosophy was simple: in a ''Great Society,'' no one is left behind. Today, that ideal lives on. Health centers provide quality medical, dental, and behavioral health care services to more than 30 million Americans each year, and they remain a cornerstone of our public health system. During National Health Center Week, we celebrate the vital role these health centers play in safeguarding the well-being of Americans and honor the heroic staff who keep these facilities running.

Health care is a right, not a privilege. Yet many people still struggle to obtain the medical services they need. Nearly 4 million Americans remain locked out of Medicaid expansion, and millions more find it difficult to afford prescription drugs, mental health services, and preventive screenings. Access to care is also often unequal—Black and Brown Americans, rural residents, American Indian and Alaska Native Tribes, and low-income families consistently report lower rates of coverage and lesser access to primary care. Federally funded health centers meet these challenges head-on by providing medical services—particularly to communities of color, rural communities, and individuals living in poverty—through nearly 1,400 community-based organizations operating over 14,000 service delivery sites. Given that clinics operate under a patient-majority governing board, health centers ensure that decisions are being directly informed and made by those being served.

Since taking office, my Administration has strengthened our Nation's health center network. Last year, we invested $7.6 billion in American Rescue Plan funds to strengthen the health center workforce, renovate facilities, and equip them with essential COVID–19 medical supplies. We also allotted $400 million from the American Rescue Plan to create a partnership between the Centers for Disease Control and Prevention and AmeriCorps to train the next generation of public health workers, including in community health centers. We prevented sickness and treated illness for millions of Americans. We helped pay salaries for over 272,000 full-time health care workers and supporting staff.

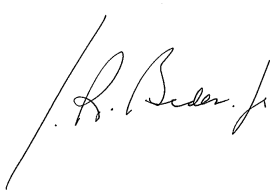
Health centers are central to many of my Administration's priorities. From reducing the cancer death rate by ensuring equitable access to cancer screenings and preventive care to helping Americans live healthier lives through new digital health technologies—we will ensure that health centers are equipped for the future of health care. I remain committed to working with the Congress to double the size of the Health Center Program, to putting even more Americans to work in these centers across our country, and to ensuring that each of us can access health care at an affordable price.

During National Health Center Week, let us recognize our health centers and staff for their outstanding contributions to communities across America.

Let us thank them for their dedication, their service, and their commitment to a stronger, healthier, and more equitable health system.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim the week of August 7 through August 13, 2022, as National Health Center Week.

IN WITNESS WHEREOF, I have hereunto set my hand this fifth day of August, in the year of our Lord two thousand twenty-two, and of the Independence of the United States of America the two hundred and forty-seventh.



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Rules and Regulations

Federal Register
Vol. 87, No. 153
Wednesday, August 10, 2022

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 63

[EPA–HQ–OAR–2008–0708; FRL–5300.3–01–OAR]

RIN 2060–AV76

National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines; New Source Performance Standards for Stationary Internal Combustion Engines; Court Vacatur

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending the Code of Federal Regulations (CFR) to reflect a 2015 court decision regarding the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Stationary Reciprocating Internal Combustion Engines (RICE) and the New Source Performance Standards (NSPS) for Stationary Internal Combustion Engines (ICE). The court vacated provisions in the regulations specifying that emergency engines could operate for emergency demand response or during periods where there is a deviation of voltage or frequency. This ministerial rule revises the RICE NESHAP and ICE NSPS to conform to the court's decision.

DATES: This final rule is effective on August 10, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2008–0708. All documents in the docket are listed in *https://www.regulations.gov/.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. With the exception of such material, publicly available docket materials are available electronically in *https://www.regulations.gov/* or in hard copy at the EPA Docket Center, Room 3334, WJC West Building, 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742. For further information and updates on EPA Docket Center services and current status, please visit us online at *https://www.epa.gov/dockets/.*

FOR FURTHER INFORMATION CONTACT: For questions about this action, contact Melanie King, Sector Policies and Programs Division (D243–01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2469; and email address: *king.melanie@epa.gov.*

SUPPLEMENTARY INFORMATION:

Organization of this document. The information in this preamble is organized as follows:

I. Why is the EPA issuing this final rule?

This action amends the CFR to reflect the 2015 court decision in *Delaware Department of Natural Resources and Environmental Control* v. *EPA,* 785 F.3d 1 (D.C. Cir. 2015) as amended (July 21, 2015), vacating 40 CFR 60.4211(f)(2)(ii) and (iii), 60.4243(d)(2)(ii) and (iii), and 63.6640(f)(2)(ii) and (iii). Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B) provides that, when an agency for good cause finds that notice and public procedures are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that there is good cause for amending these provisions without prior proposal and opportunity for public procedures because the correction of the CFR is a ministerial act to effectuate the court order and public notice and comment is unnecessary and would serve no useful purpose. Removal of the vacated paragraphs in the RICE NESHAP (40 CFR part 63 subpart ZZZZ) at 63.6640(f)(2)(ii) and (iii), the Compression Ignition (CI) ICE NSPS (40 CFR part 60 subpart IIII) at 40 CFR 60.4211(f)(2)(ii) and (iii), and the Spark Ignition (SI) ICE NSPS (40 CFR part 60 subpart JJJJ) at 60.4243(d)(2)(ii) and (iii) has no legal effect beyond fulfilling the court's vacatur in *Delaware* v. *EPA* and is ministerial in nature. The court issued the mandate for its decision on May 4, 2016, at which point the vacatur became effective.

II. Background

The RICE NESHAP and ICE NSPS include a subcategory for emergency engines and specify that to be classified as an emergency engine, an engine must meet certain limitations on its hours of operation in non-emergency situations. The existing regulations provide that hours of operation in non-emergency situations are limited to 100 hours per year and only allowed for specific purposes. On January 30, 2013, the EPA finalized amendments to the RICE NESHAP and ICE NSPS specifying that the non-emergency situations in which emergency engines could be operated included (1) for emergency demand response during periods in which the Reliability Coordinator under the North American Electric Reliability

Corporation (NERC) Reliability Standard EOP–002–3, Capacity and Energy Emergencies, or other authorized entity as determined by the Reliability Coordinator, has declared an Energy Emergency Alert Level 2 as defined in the NERC Reliability Standard EOP–002–3 and (2) periods where there is a deviation of voltage or frequency of 5 percent or greater below standard voltage or frequency. 78 FR 6674, January 30, 2013. The state of Delaware and other industry and environmental groups filed petitions seeking judicial review of the provisions specifying that emergency engines could operate for emergency demand response and during voltage or frequency deviations. In response to these petitions, the U.S. Court of Appeals for the District of Columbia Circuit vacated those provisions in the RICE NESHAP and ICE NSPS in 2015. The court held that the EPA acted arbitrarily and capriciously when it modified the RICE NESHAP and ICE NSPS to specify that emergency engines could operate for up to 100 hours per year for emergency demand response. The court granted the EPA's motion to stay issuance of its mandate until May 2016 to allow engine owners to take the necessary measures to bring their engines into compliance with the regulations. Upon issuance of the court's mandate, the vacated provisions ceased to have any legal effect, and engines that were operating for any number of hours per year for the circumstances described in the vacated provisions were required to cease operation under such circumstances or comply with the emission standards and other applicable requirements for non-emergency engines. The EPA issued a guidance memorandum explaining the effect of the vacatur [1] and is now amending the RICE NESHAP and ICE NSPS to reflect the court decision.

III. Which provisions are being amended?

This final rule amends the RICE NESHAP by removing paragraphs 40 CFR 63.6640(f)(2)(ii) and (iii), the CI ICE NSPS by removing paragraphs 40 CFR 60.4211(f)(2)(ii) and (iii), and the SI ICE NSPS by removing paragraphs 40 CFR 60.4243(d)(2)(ii) and (iii), all of which were vacated by the *Delaware* v. *EPA* decision. The removal of the vacated paragraphs also necessitates revisions to other paragraphs in the ICE NSPS and RICE NESHAP that contained references to the vacated paragraphs or referenced operation of engines categorized as emergency engines for the purpose of emergency demand response, which can no longer occur due to the vacatur. A list of these revisions is provided below.

- *40 CFR 60.4211(f):* Remove ''emergency demand response'' from the paragraph (f) introductory text and the paragraph (f)(3) introductory text since operation for emergency demand response is no longer allowed for emergency engines; remove reference to the vacated paragraphs (f)(2)(ii) and (iii) from the paragraph (f)(2) introductory text.
- *40 CFR 60.4214(d):* Remove the reference in the paragraph (d) introductory text to operating for the purposes specified in the vacated paragraphs 40 CFR 60.4211(f)(2)(ii) and (iii); remove paragraphs (v) and (vi) which required reporting of operation and contractual obligation for the purposes specified in the vacated paragraphs.
- *40 CFR 60.4219:* Revise definition for ''emergency stationary internal combustion engine'' to remove reference to the vacated paragraphs 40 CFR 60.4211(f)(2)(ii) and (iii) in paragraph (3) of the definition.
- *40 CFR 60.4243(d):* Remove ''emergency demand response'' from the paragraph (d) introductory text and the paragraph (d)(3) introductory text since operation for emergency demand response is no longer allowed for emergency engines; remove reference to the vacated paragraphs (d)(2)(ii) and (iii) from the paragraph (d)(2) introductory text.
- *40 CFR 60.4245(e):* Remove the reference in the paragraph (e) introductory text to operating for the purposes specified in the vacated paragraphs 40 CFR 60.4243(d)(2)(ii) and (iii); remove paragraphs (v) and (vi) which required reporting of operation and contractual obligation for the purposes specified in the vacated paragraphs.
- *40 CFR 60.4248:* Revise definition for ''emergency stationary internal combustion engine'' to remove reference to the vacated paragraphs 40 CFR 60.4243(d)(2)(ii) and (iii) in paragraph (3) of the definition.
- *40 CFR 63.6585:* Remove reference to operation and contractual obligation for the purposes specified in the vacated paragraphs 40 CFR 63.6640(f)(2)(ii) and (iii).
- *40 CFR 63.6590:* Remove references in paragraphs (b)(1)(i) and (b)(3)(iii) to operation and contractual obligation for the purposes specified in the vacated paragraphs 40 CFR 63.6640(f)(2)(ii) and (iii).
- *40 CFR 63.6604:* Remove reference in paragraph (b) to operation and contractual obligation for the purposes specified in the vacated paragraphs 40 CFR 63.6640(f)(2)(ii) and (iii); remove paragraph (c) since it only applied to an emergency engine that operates or is contractually obligated to be available for the purposes specified in the vacated paragraphs 40 CFR 63.6640(f)(2)(ii) and (iii) and there would no longer be any emergency engines meeting that criteria since operation for those purposes is no longer allowed for emergency engines.
- *40 CFR 63.6640:* Remove ''emergency demand response'' from the paragraph (f) introductory text, the paragraph (f)(3) introductory text, and the paragraph (f)(4) introductory text since operation for emergency demand response is no longer allowed for emergency engines; remove reference to the vacated paragraphs (f)(2)(ii) and (iii) from the paragraph (f)(2) introductory text.
- *40 CFR 63.6650:* Remove the reference in the paragraph (h) introductory text to operating for the purposes specified in the vacated paragraphs 40 CFR 63.6640(f)(2)(ii) and (iii); remove paragraphs (v) and (vi) which required reporting of operation and contractual obligation for the purposes specified in the vacated paragraphs.
- *40 CFR 63.6655:* Remove reference in paragraph (f) to the vacated paragraphs 40 CFR 63.6640(f)(2)(ii) and (iii).
- *40 CFR 63.6675:* Revise definition for ''emergency stationary RICE'' to remove reference to the vacated paragraphs 40 CFR 63.6640(f)(2)(ii) and (iii) in paragraph (3) of the definition.
- *Table 7 to subpart ZZZZ:* Remove reference in item 4 to operating for the purposes specified in the vacated paragraphs 40 CFR 63.6640(f)(2)(ii) and (iii).

As explained above, removal of these provisions corrects the CFR to conform to the court's decision in *Delaware* v. *EPA* and is ministerial in nature and neither imposes or removes any new requirements.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

[1] *Guidance on Vacatur of RICE NESHAP and NSPS Provisions for Emergency Engines.* Peter Tsirigotis, OAQPS to EPA Regional Air Enforcement Managers and Regional Air Directors. April 15, 2016. *https://www.epa.gov/sites/default/files/2016-06/documents/ricevacaturguidance041516.pdf.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule has no net burden on the small entities subject to the rule. This action is ministerial in nature as it codifies a court-issued mandate vacating regulatory provisions. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. This action presents no additional burden on implementing authorities beyond existing requirements. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This regulatory action is ministerial in nature as it codifies a court issued mandate vacating regulatory provisions and does not have any impact on human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and comment rulemaking procedures are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule in section I of this preamble, including the basis for that finding.

List of Subjects

40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, 40 CFR parts 60 and 63 are amended as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.* 42 U.S.C. 7401–7601.

Subpart IIII—Standards of Performance for Stationary Compression Ignition Internal Combustion Engines

■ 2. In § 60.4211:

■ a. Revise paragraphs (f) introductory text and (f)(2) introductory text;

■ b. Remove and reserve paragraphs (f)(2)(ii) and (iii); and

■ c. Revise paragraph (f)(3) introductory text.

The revisions read as follows:

§ 60.4211 What are my compliance requirements if I am an owner or operator of a stationary CI internal combustion engine?

* * * * *

(f) If you own or operate an emergency stationary ICE, you must operate the emergency stationary ICE according to the requirements in paragraphs (f)(1) through (3) of this section. In order for the engine to be considered an emergency stationary ICE under this subpart, any operation other than emergency operation, maintenance and testing, and operation in non-emergency situations for 50 hours per year, as described in paragraphs (f)(1) through (3), is prohibited. If you do not operate the engine according to the requirements in paragraphs (f)(1) through (3), the engine will not be considered an emergency engine under this subpart and must meet all requirements for non-emergency engines.

* * * * *

(2) You may operate your emergency stationary ICE for the purpose specified in paragraph (f)(2)(i) of this section for a maximum of 100 hours per calendar year. Any operation for non-emergency situations as allowed by paragraph (f)(3) of this section counts as part of the 100

hours per calendar year allowed by this paragraph (f)(2).

* * * * *

(3) Emergency stationary ICE may be operated for up to 50 hours per calendar year in non-emergency situations. The 50 hours of operation in non-emergency situations are counted as part of the 100 hours per calendar year for maintenance and testing provided in paragraph (f)(2) of this section. Except as provided in paragraph (f)(3)(i) of this section, the 50 hours per calendar year for non-emergency situations cannot be used for peak shaving or non-emergency demand response, or to generate income for a facility to an electric grid or otherwise supply power as part of a financial arrangement with another entity.

* * * * *

■ 3. Section 60.4214 is amended by revising paragraph (d) introductory text and removing and reserving paragraphs (d)(1)(v) and (vi).

The revision reads as follows:

§ 60.4214 What are my notification, reporting, and recordkeeping requirements if I am an owner or operator of a stationary CI internal combustion engine?

* * * * *

(d) If you own or operate an emergency stationary CI ICE with a maximum engine power more than 100 HP that operates for the purpose specified in § 60.4211(f)(3)(i), you must submit an annual report according to the requirements in paragraphs (d)(1) through (3) of this section.

* * * * *

■ 4. Section 60.4219 is amended by revising the definition ''Emergency stationary internal combustion engine'' to read as follows:

§ 60.4219 What definitions apply to this subpart?

* * * * *

Emergency stationary internal combustion engine means any stationary reciprocating internal combustion engine that meets all of the criteria in paragraphs (1) through (3) of this definition. All emergency stationary ICE must comply with the requirements specified in § 60.4211(f) in order to be considered emergency stationary ICE. If the engine does not comply with the requirements specified in § 60.4211(f), then it is not considered to be an emergency stationary ICE under this subpart.

(1) The stationary ICE is operated to provide electrical power or mechanical work during an emergency situation. Examples include stationary ICE used to produce power for critical networks or equipment (including power supplied to portions of a facility) when electric power from the local utility (or the normal power source, if the facility runs on its own power production) is interrupted, or stationary ICE used to pump water in the case of fire or flood, etc.

(2) The stationary ICE is operated under limited circumstances for situations not included in paragraph (1) of this definition, as specified in § 60.4211(f).

(3) The stationary ICE operates as part of a financial arrangement with another entity in situations not included in paragraph (1) of this definition only as allowed in § 60.4211(f)(3)(i).

* * * * *

Subpart JJJJ—Standards of Performance for Stationary Spark Ignition Internal Combustion Engines

■ 5. In § 60.4243:

■ a. Revise paragraphs (d) introductory text and (d)(2) introductory text;

■ b. Remove and reserve paragraphs (d)(2)(ii) and (iii); and

■ c. Revise paragraph (d)(3) introductory text.

The revisions read as follows:

§ 60.4243 What are my compliance requirements if I am an owner or operator of a stationary SI internal combustion engine?

* * * * *

(d) If you own or operate an emergency stationary ICE, you must operate the emergency stationary ICE according to the requirements in paragraphs (d)(1) through (3) of this section. In order for the engine to be considered an emergency stationary ICE under this subpart, any operation other than emergency operation, maintenance and testing, and operation in non-emergency situations for 50 hours per year, as described in paragraphs (d)(1) through (3), is prohibited. If you do not operate the engine according to the requirements in paragraphs (d)(1) through (3), the engine will not be considered an emergency engine under this subpart and must meet all requirements for non-emergency engines.

* * * * *

(2) You may operate your emergency stationary ICE for the purpose specified in paragraph (d)(2)(i) of this section for a maximum of 100 hours per calendar year. Any operation for non-emergency situations as allowed by paragraph (d)(3) of this section counts as part of the 100 hours per calendar year allowed by this paragraph (d)(2).

* * * * *

(3) Emergency stationary ICE may be operated for up to 50 hours per calendar year in non-emergency situations. The 50 hours of operation in non-emergency situations are counted as part of the 100 hours per calendar year for maintenance and testing provided in paragraph (d)(2) of this section. Except as provided in paragraph (d)(3)(i) of this section, the 50 hours per year for non-emergency situations cannot be used for peak shaving or non-emergency demand response, or to generate income for a facility to an electric grid or otherwise supply power as part of a financial arrangement with another entity.

* * * * *

■ 6. Section 60.4245 is amended by revising paragraph (e) introductory text and removing and reserving paragraphs (e)(1)(v) and (vi).

The revision reads as follows:

§ 60.4245 What are my notification, reporting, and recordkeeping requirements if I am an owner or operator of a stationary SI internal combustion engine?

* * * * *

(e) If you own or operate an emergency stationary SI ICE with a maximum engine power more than 100 HP that operates for the purpose specified in § 60.4243(d)(3)(i), you must submit an annual report according to the requirements in paragraphs (e)(1) through (3) of this section.

* * * * *

■ 7. Section 60.4248 is amended by revising the definition ''Emergency stationary internal combustion engine'' to read as follows:

§ 60.4248 What definitions apply to this subpart?

* * * * *

Emergency stationary internal combustion engine means any stationary reciprocating internal combustion engine that meets all of the criteria in paragraphs (1) through (3) of this definition. All emergency stationary ICE must comply with the requirements specified in § 60.4243(d) in order to be considered emergency stationary ICE. If the engine does not comply with the requirements specified in § 60.4243(d), then it is not considered to be an emergency stationary ICE under this subpart.

(1) The stationary ICE is operated to provide electrical power or mechanical work during an emergency situation. Examples include stationary ICE used to produce power for critical networks or equipment (including power supplied to portions of a facility) when electric power from the local utility (or the normal power source, if the facility runs on its own power production) is

interrupted, or stationary ICE used to pump water in the case of fire or flood, etc.

(2) The stationary ICE is operated under limited circumstances for situations not included in paragraph (1) of this definition, as specified in § 60.4243(d).

(3) The stationary ICE operates as part of a financial arrangement with another entity in situations not included in paragraph (1) of this definition only as allowed in § 60.4243(d)(3)(i).

* * * * *

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 8. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart ZZZZ—National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines

■ 9. Section 63.6585 is amended by revising paragraphs (f)(1) through (3) to read as follows:

§ 63.6585 Am I subject to this subpart?

* * * * *

(f) * * *

(1) Existing residential emergency stationary RICE located at an area source of HAP emissions that do not operate for the purpose specified in § 63.6640(f)(4)(ii).

(2) Existing commercial emergency stationary RICE located at an area source of HAP emissions that do not operate for the purpose specified in § 63.6640(f)(4)(ii).

(3) Existing institutional emergency stationary RICE located at an area source of HAP emissions that do not operate for the purpose specified in § 63.6640(f)(4)(ii).

■ 10. Section 63.6590 is amended by revising paragraphs (b)(1)(i) and (b)(3)(iii) to read as follows:

§ 63.6590 What parts of my plant does this subpart cover?

* * * * *

(b) * * *

(1) * * *

(i) The stationary RICE is a new or reconstructed emergency stationary RICE with a site rating of more than 500 brake HP located at a major source of HAP emissions.

* * * * *

(3) * * *

(iii) Existing emergency stationary RICE with a site rating of more than 500 brake HP located at a major source of HAP emissions.

* * * * *

■ 11. Section 63.6604 is amended by revising paragraph (b) and removing and reserving paragraph (c).

The revision reads as follows:

§ 63.6604 What fuel requirements must I meet if I own or operate a stationary CI RICE?

* * * * *

(b) Beginning January 1, 2015, if you own or operate an existing emergency CI stationary RICE with a site rating of more than 100 brake HP and a displacement of less than 30 liters per cylinder that uses diesel fuel and operates for the purpose specified in § 63.6640(f)(4)(ii), you must use diesel fuel that meets the requirements in 40 CFR 1090.305 for nonroad diesel fuel, except that any existing diesel fuel purchased (or otherwise obtained) prior to January 1, 2015, may be used until depleted.

* * * * *

■ 12. In § 63.6640:

■ a. Revise paragraphs (f) introductory text and (f)(2) introductory text;

■ c. Remove and reserve paragraphs (f)(2)(ii) and (iii); and

■ d. Revise paragraph (f)(3) and paragraph (f)(4) introductory text.

The revisions read as follows:

§ 63.6640 How do I demonstrate continuous compliance with the emission limitations, operating limitations, and other requirements?

* * * * *

(f) If you own or operate an emergency stationary RICE, you must operate the emergency stationary RICE according to the requirements in paragraphs (f)(1) through (4) of this section. In order for the engine to be considered an emergency stationary RICE under this subpart, any operation other than emergency operation, maintenance and testing, and operation in non-emergency situations for 50 hours per year, as described in paragraphs (f)(1) through (4), is prohibited. If you do not operate the engine according to the requirements in paragraphs (f)(1) through (4), the engine will not be considered an emergency engine under this subpart and must meet all requirements for non-emergency engines.

* * * * *

(2) You may operate your emergency stationary RICE for the purpose specified in paragraph (f)(2)(i) of this section for a maximum of 100 hours per calendar year. Any operation for non-emergency situations as allowed by paragraphs (f)(3) and (4) of this section counts as part of the 100 hours per calendar year allowed by this paragraph (f)(2).

* * * * *

(3) Emergency stationary RICE located at major sources of HAP may be operated for up to 50 hours per calendar year in non-emergency situations. The 50 hours of operation in non-emergency situations are counted as part of the 100 hours per calendar year for maintenance and testing provided in paragraph (f)(2) of this section. The 50 hours per year for non-emergency situations cannot be used for peak shaving or non-emergency demand response, or to generate income for a facility to supply power to an electric grid or otherwise supply power as part of a financial arrangement with another entity.

(4) Emergency stationary RICE located at area sources of HAP may be operated for up to 50 hours per calendar year in non-emergency situations. The 50 hours of operation in non-emergency situations are counted as part of the 100 hours per calendar year for maintenance and testing provided in paragraph (f)(2) of this section. Except as provided in paragraphs (f)(4)(i) and (ii) of this section, the 50 hours per year for non-emergency situations cannot be used for peak shaving or non-emergency demand response, or to generate income for a facility to an electric grid or otherwise supply power as part of a financial arrangement with another entity.

* * * * *

■ 13. Section 63.6650 is amended by revising paragraph (h) introductory text and removing and reserving paragraphs (h)(1)(v) and (vi).

The revision reads as follows:

§ 63.6650 What reports must I submit and when?

* * * * *

(h) If you own or operate an emergency stationary RICE with a site rating of more than 100 brake HP that operates for the purpose specified in § 63.6640(f)(4)(ii), you must submit an annual report according to the requirements in paragraphs (h)(1) through (3) of this section.

* * * * *

■ 14. Section 63.6655 is amended by revising paragraph (f) introductory text to read as follows:

§ 63.6655 What records must I keep?

* * * * *

(f) If you own or operate any of the stationary RICE in paragraphs (f)(1) through (2) of this section, you must keep records of the hours of operation of the engine that is recorded through the non-resettable hour meter. The

owner or operator must document how many hours are spent for emergency operation, including what classified the operation as emergency and how many hours are spent for non-emergency operation. If the engine is used for the purpose specified in § 63.6640(f)(4)(ii), the owner or operator must keep records of the notification of the emergency situation, and the date, start time, and end time of engine operation for these purposes.

* * * * *

■ 15. Section 63.6675 is amended by revising the definition ''Emergency stationary RICE'' to read as follows:

§ 63.6675 What definitions apply to this subpart?

* * * * *

Emergency stationary RICE means any stationary reciprocating internal combustion engine that meets all of the criteria in paragraphs (1) through (3) of this definition. All emergency stationary RICE must comply with the requirements specified in § 63.6640(f) in order to be considered emergency stationary RICE. If the engine does not comply with the requirements specified in § 63.6640(f), then it is not considered to be an emergency stationary RICE under this subpart.

(1) The stationary RICE is operated to provide electrical power or mechanical work during an emergency situation. Examples include stationary RICE used to produce power for critical networks or equipment (including power supplied to portions of a facility) when electric power from the local utility (or the normal power source, if the facility runs on its own power production) is interrupted, or stationary RICE used to pump water in the case of fire or flood, etc.

(2) The stationary RICE is operated under limited circumstances for situations not included in paragraph (1) of this definition, as specified in § 63.6640(f).

(3) The stationary RICE operates as part of a financial arrangement with another entity in situations not included in paragraph (1) of this definition only as allowed in § 63.6640(f)(4)(i) or (ii).

* * * * *

■ 16. Table 7 to subpart ZZZZ of part 63 is revised to read as follows:

Table 7 to Subpart ZZZZ of Part 63—Requirements for Reports

As stated in § 63.6650, you must comply with the following requirements for reports:

For each . . .	You must submit a . . .	The report must contain . . .	You must submit the report . . .
1. Existing non-emergency, non-black start stationary RICE 100≤HP≤500 located at a major source of HAP; existing non-emergency, non-black start stationary CI RICE >500 HP located at a major source of HAP; existing non-emergency 4SRB stationary RICE >500 HP located at a major source of HAP; existing non-emergency, non-black start stationary CI RICE >300 HP located at an area source of HAP; new or reconstructed non-emergency stationary RICE >500 HP located at a major source of HAP; and new or reconstructed non-emergency 4SLB stationary RICE 250≤HP≤500 located at a major source of HAP.	Compliance report	a. If there are no deviations from any emission limitations or operating limitations that apply to you, a statement that there were no deviations from the emission limitations or operating limitations during the reporting period. If there were no periods during which the CMS, including CEMS and CPMS, was out-of-control, as specified in § 63.8(c)(7), a statement that there were not periods during which the CMS was out-of-control during the reporting period; or	i. Semiannually according to the requirements in § 63.6650(b)(1)–(5) for engines that are not limited use stationary RICE subject to numerical emission limitations; and ii. Annually according to the requirements in § 63.6650(b)(6)–(9) for engines that are limited use stationary RICE subject to numerical emission limitations.
		b. If you had a deviation from any emission limitation or operating limitation during the reporting period, the information in § 63.6650(d). If there were periods during which the CMS, including CEMS and CPMS, was out-of-control, as specified in § 63.8(c)(7), the information in § 63.6650(e); or	i. Semiannually according to the requirements in § 63.6650(b).
		c. If you had a malfunction during the reporting period, the information in § 63.6650(c)(4)	i. Semiannually according to the requirements in § 63.6650(b).
2. New or reconstructed non-emergency stationary RICE that combusts landfill gas or digester gas equivalent to 10 percent or more of the gross heat input on an annual basis.	Report	a. The fuel flow rate of each fuel and the heating values that were used in your calculations, and you must demonstrate that the percentage of heat input provided by landfill gas or digester gas, is equivalent to 10 percent or more of the gross heat input on an annual basis; and	i. Annually, according to the requirements in § 63.6650.
		b. The operating limits provided in your federally enforceable permit, and any deviations from these limits; and	i. See item 2.a.i.
		c. Any problems or errors suspected with the meters.	i. See item 2.a.i.
3. Existing non-emergency, non-black start 4SLB and 4SRB stationary RICE >500 HP located at an area source of HAP that are not remote stationary RICE and that operate more than 24 hours per calendar year.	Compliance report	a. The results of the annual compliance demonstration, if conducted during the reporting period.	i. Semiannually according to the requirements in § 63.6650(b)(1)–(5).
4. Emergency stationary RICE that operate for the purposes specified in § 63.6640(f)(4)(ii).	Report	a. The information in § 63.6650(h)(1)	i. annually according to the requirements in § 63.6650(h)(2)–(3).

[FR Doc. 2022–17060 Filed 8–9–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410 and 414

[CMS–6087–N]

Medicare Program; Suspension of Required Prior Authorization for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items Under Certain Circumstances

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, (HHS).

ACTION: Suspension of prior authorization requirements for specified orthoses prescribed and furnished urgently or under special circumstances.

SUMMARY: This document announces the suspension of prior authorization for specified orthoses items on the Required Prior Authorization List that require prior authorization as a condition of payment under certain circumstances when reported with certain modifiers. Items subject to face-to-face encounter and written order prior to delivery requirements are not impacted by this document.

DATES: The suspension of the prior authorization requirement discussed in this document took effect on April 13, 2022, when CMS published an announcement on its website.

FOR FURTHER INFORMATION CONTACT: Emily Calvert, (410) 786–4277.

SUPPLEMENTARY INFORMATION:

I. Background

In the December 30, 2015, final rule (80 FR 81674) titled, ''Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,'' we implemented section 1834(a)(15) of the Act by establishing an initial Master List (called the Master List of Items Frequently Subject to Unnecessary Utilization) of certain DMEPOS that the Secretary determined, on the basis of prior payment experience, are frequently subject to unnecessary utilization and by establishing a prior authorization process for these items.

In the November 8, 2019, **Federal Register** (84 FR 60648), we published a final rule titled, ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements.'' Through this November 2019 final rule, we harmonized the lists of DMEPOS items created by former rules and established one ''Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements'' (the ''Master List''). The November 2019 final rule was effective January 1, 2020.

In January 13, 2022, **Federal Register** (87 FR 2051), we published a document, titled, ''Medicare Program; Updates to Lists Related to Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Conditions of Payment.'' Through the January 2022 **Federal Register** document, we updated the Master List and selected certain lower limb orthoses, lumbar sacral orthoses, and power mobility devices to be subject to required prior authorization. The January 2022 **Federal Register** document was effective April 13, 2022.

II. Provisions of the Document

In accordance with 42 CFR 414.234(f), CMS may suspend DMEPOS prior authorization requirement generally or for a particular item or items at any time and without undertaking rulemaking. Due to the need for certain patients to receive an orthoses item that may otherwise be subject to prior authorization when the 2-day expedited review would delay care and risk the health or life of the beneficiary, we are suspending prior authorization requirements indefinitely, under these limited circumstances:

- Claims for HCPCS codes L0648, L0650, L1832, L1833, and L1851 that are billed using modifier ST, indicating that the item was furnished urgently.
- Claims for HCPCS codes L0648, L0650, L1833, and L1851 billed with modifiers KV, J5, or J4, by suppliers furnishing these items under a competitive bidding program exception (as described in 42 CFR 414.404(b)), to convey that the DMEPOS item is needed immediately either because it is being furnished by a physician or treating practitioner during an office visit where the physician or treating practitioner determines that the brace is needed immediately due to medical necessity or because it is being furnished by an occupational therapist or physical therapist who determines that the brace needs to be furnished as part of a therapy session(s).

Prior authorization will continue for these orthoses items (HCPCS L0648, L0650, L1832, L1833, and L1851) when furnished under circumstances not covered in this update, as well as all other items on the Required Prior Authorization List, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Downloads/DMEPOS_PA_Required-Prior-Authorization-List.pdf.*

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: August 5, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–17187 Filed 8–9–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–5537–N]

Medicare Program; Alternative Payment Model (APM) Incentive Payment Advisory for Clinicians—Request for Current Billing Information for Qualifying APM Participants

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Payment advisory.

SUMMARY: This advisory is to alert certain clinicians who are Qualifying APM participants (QPs) and eligible to receive an Alternative Payment Model (APM) Incentive Payment that CMS does not have the current billing information needed to disburse the payment. This advisory provides information to these clinicians on how to update their billing information to receive this payment.

DATES: Updated billing information must be received no later than November 1, 2022 (see **SUPPLEMENTARY INFORMATION** for details).

FOR FURTHER INFORMATION CONTACT: Tanya Dorm, (410) 786–2216.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare Quality Payment Program, an eligible clinician who participates in an Advanced Alternative Payment Model (APM) and meets the applicable payment amount or patient count thresholds for a performance year is a Qualifying APM Participant (QP) for that year. For payment years 2019 through 2024, an eligible clinician who is a QP for a year based on their performance in a QP Performance Period earns a 5-percent lump sum APM Incentive Payment that is paid in a payment year that occurs 2 years after the QP Performance Period. The amount of the APM Incentive Payment is equal to 5 percent of the estimated aggregate paid amounts for covered professional services furnished by the QP during the calendar year immediately preceding the payment year.

II. Provisions of the Advisory

The Centers for Medicare & Medicaid Services (CMS) has identified those eligible clinicians who earned an APM Incentive Payment in CY 2022 based on their CY 2020 QP status.

When we disbursed the CY 2022 APM Incentive Payments, we were unable to verify current Medicare billing information for some QPs and therefore unable to issue the payment. In order to properly disburse the APM Incentive Payment, CMS is requesting assistance in identifying current Medicare billing information for these QPs in accordance with 42 CFR 414.1450(c)(8).

We have compiled a list of QPs we have identified as having unverified billing information. These QPs, and any others who anticipated receiving an APM Incentive Payment but have not, should follow the instructions to provide CMS with updated billing information at the following web address: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1968/2022%20QP%20Notice%20for%20APM%20Incentive%20Payment%20Zip%20File.zip.*

If you have any questions concerning submission of information through the website, please contact the Quality Payment Program Help Desk at 1–866–288–8292.

All submissions must be received no later than November 1, 2022. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for the CY 2022 payment year. To make sure we have received all updated billing forms, we will process remaining CY 2022 APM Incentive Payments during one payment cycle in the beginning of 2023, based on updated billing information for QPs received by November 1, 2022. Payment processing occurs one time after all forms have been received.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: August 5, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–17186 Filed 8–9–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 100217095–2081–04; RTID 0648–XC199]

Reef Fish Fishery of the Gulf of Mexico; 2022 Recreational Accountability Measure and Closure for Gulf of Mexico Red Grouper

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) for the red grouper recreational sector in the exclusive economic zone (EEZ) of the Gulf of Mexico (Gulf) for the 2022 fishing year through this temporary rule. NMFS has projected that the 2022 recreational annual catch target (ACT) for Gulf red grouper will have been reached by August 30, 2022. Therefore, NMFS closes the recreational sector for Gulf red grouper on August 30, 2022, and it will remain closed through the end of the fishing year on December 31, 2022. This closure is necessary to protect the Gulf red grouper resource.

DATES: This temporary rule is effective from 12:01 a.m., local time, on August 30, 2022, until 12:01 a.m., local time, on January 1, 2023.

FOR FURTHER INFORMATION CONTACT: Dan Luers, NMFS Southeast Regional Office, telephone: 727–551–5719, email: *daniel.luers@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS manages the Gulf reef fish fishery, which includes red grouper, under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The FMP was prepared by the Gulf of Mexico Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) through regulations at 50 CFR part 622. All red grouper weights discussed in this temporary rule are in gutted weight.

Following a recent red grouper stock assessment, NMFS implemented Amendment 53 to the Reef Fish FMP (87 FR 25573, May 2, 2022), which modified the allocation between the commercial and recreational sectors, and the sector catch limits. The new assessment incorporated updated historical recreational landings estimates calibrated to the Marine Recreational Information Program (MRIP) Fishing Effort Survey (FES), the current method for estimating recreational effort. The previous recreational catch limits were based on an assessment that incorporated the historical recreational landings estimates generated using the prior (MRIP) Coastal Household Telephone Survey (CHTS), which produced significantly lower estimates of recreational effort. Under Amendment 53, the recreational annual catch limit (ACL) is 1.73 million lb (0.78 million kg) and the recreational ACT is 1.57 million lb (0.71 kg)(in MRIP FES units). Subsequent to the Amendment 53 final rule, NMFS implemented a final rule for a framework action under the FMP (87 FR 40742, July 8, 2022) which further revised the red grouper recreational ACL to 2.02 million lb (0.92 million kg) and the ACT to 1.84 million lb (0.83 million kg). This rule is effective August 8, 2022.

The Gulf red grouper recreational ACL was exceeded in 2021 by approximately 0.72 million lb (0.33 million kg) or 72 percent of the recreational ACL. As specified in 50 CFR 622.41(e)(2)(ii), in the year following a recreational ACL overage, NMFS is required to maintain the red grouper ACT in that following fishing year at the level of the prior year's ACT, unless the best scientific information available determines that maintaining

the prior year's ACT is unnecessary. In addition, NMFS is required to reduce the length of that following year's recreational fishing season to ensure that the recreational ACT is not exceeded in that following year.

Although the regulations refer to maintaining the prior year's ACT, the 2021 ACT is not consistent with catch limits established in Amendment 53 and the 2022 red grouper framework action because it was derived from an assessment that used the outdated MRIP CHTS historical recreational landings estimates and the prior commercial-recreational allocation. In addition, as explained in the final rule implementing Amendment 53, the 2021 ACT, which is 0.92 million lb (0.42 million kg) in MRIP CHTS units, would be 1.93 million lb (0.88 million kg) in MRIP FES units (87 FR at 25574). This is greater than the current 2022 ACT of 1.84 million lb (0.83 million kg), and implementing a closure based on the greater ACT would increase the likelihood of exceeding the 2022 recreational ACL. Therefore, this closure is based on the projection of when the newly implemented ACT for 2022 will be reached. Based on data from January–April 2022, and on the average harvest rates for the 2020 and 2021 recreational fishing years, NMFS projects that the 2022 recreational ACT for Gulf red grouper will be reached as of August 30, 2022. NMFS used a 2-year average for the projected harvest rates because NMFS determined that it is most representative of current conditions. The catch rate in 2021 was higher than the catch rate in 2020. However, the harvest of red grouper from January through April of 2022 was lower than in 2021, and the price of fuel may be contributing to less boating/fishing activity to date in 2022. Accordingly, this temporary rule closes the recreational sector for Gulf red grouper effective at 12:01 a.m., local time, on August 30, 2022, through the end of the fishing year on December 31, 2022.

During the recreational closure, the bag and possession limits for red grouper in or from the Gulf EEZ are zero. The prohibition on possession of Gulf red grouper also applies in Gulf state waters for any vessel issued a valid Federal charter vessel/headboat permit for Gulf reef fish.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.41(e)(2)(i), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment is unnecessary and contrary to the public interest. Such procedures are unnecessary because the regulations associated with the closure of the red grouper recreational sector at 50 CFR 622.41(e)(2)(i) have already been subject to notice and public comment, and all that remains is to notify the public of the closure. Prior notice and opportunity for public comment are contrary to the public interest because there is a need to immediately implement this action to protect the red grouper stock. Prior notice and opportunity for public comment would require time and could result in a harvest well in excess of the established ACT and ACL.

For the aforementioned reasons, the Assistant Administrator also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 5, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–17157 Filed 8–5–22; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 220223–0054; RTID 0648–XC235]

Fisheries of the Exclusive Economic Zone Off Alaska; Blackspotted and Rougheye Rockfish in the Central Aleutian and Western Aleutian Districts of the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of blackspotted and rougheye rockfish in the Central Aleutian and Western Aleutian districts (CAI/WAI) of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary because the 2022 blackspotted and rougheye rockfish total allowable catch (TAC) in the CAI/WAI of the BSAI has been reached.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), August 6, 2022, through 2400 hours, A.l.t., December 31, 2022.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2022 blackspotted and rougheye rockfish TAC in the CAI/WAI of the BSAI is 177 metric tons (mt) as established by the final 2022 and 2023 harvest specifications for groundfish in the BSAI (87 FR 11626, March 2, 2022) and inseason action (87 FR 43220, July 20,2022). In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2022 blackspotted and rougheye rockfish TAC in the CAI/WAI of the BSAI has been reached. Therefore, NMFS is requiring that blackspotted and rougheye rockfish in the CAI/WAI of the BSAI be treated in the same manner as a prohibited species, as described under § 679.21(a), for the remainder of the year, except blackspotted and rougheye rockfish species in the CAI/WAI caught by catcher vessels using hook-and-line, pot, or jig gear as described in § 679.20(j).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the prohibited retention of blackspotted and rougheye rockfish in the CAI/WAI of the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data

only became available as of August 4, 2022.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 5, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–17160 Filed 8–5–22; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 153
Wednesday, August 10, 2022

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 502, 556, and 558

RIN 3141–AA32

Definitions; Background Investigation for Primary Management Officials and Key Employees; Gaming Licenses for Primary Management Officials and Key Employees

AGENCY: National Indian Gaming Commission, Department of the Interior.

ACTION: Proposed rule.

SUMMARY: The National Indian Gaming Commission proposes to amend its regulations to add definitions, amend existing definitions, and amend requirements for conducting background investigations and issuing licenses. Proposed amendments include adding general managers and other persons with similar management responsibility to the primary management official definition; limiting the definition to those with duties similar to those of a chief financial officer rather than persons who have financial management responsibility; and limiting primary management officials to employed management officials designated by Tribes instead of any person so designated. The proposed amendments to the key employee definition consolidate certain of its subsections; include gaming operation employees authorized for unescorted access to secured areas that are designated as such by Tribal gaming regulatory authorities; remove compensation as determinative factor with the exception of the four most highly compensated persons in the gaming operation; and allow Tribes to designate any other employee of the gaming enterprise as a key employee instead of ''any other person.'' Other proposed amendments incorporate the addition definitions for Gaming Enterprise and Tribal Gaming Regulatory Authority and clarify licensing application and background investigation retention. Specifically, the proposed amendments focus on licensing of primary management officials and key employees instead of employment of them; adding notification requirements for licensing revocation decisions; specifying retention requirements of information and documentation post termination; and changing the vesting of a right to a hearing to reflect Tribal law and policy.

DATES: Written comments on this proposed rule must be received on or before September 9, 2022.

ADDRESSES: You may submit comments by any one of the following methods, however, please note that comments sent by electronic mail are strongly encouraged.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email comments to: information@nigc.gov.*
- *Mail comments to:* National Indian Gaming Commission, 1849 C Street NW, MS 1621, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Michael Hoenig at (202) 420–9241.

SUPPLEMENTARY INFORMATION:

I. Background and Development of the Rule

A. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (''NIGC'' or ''Commission'') and set out a comprehensive framework for the regulation of gaming on Indian lands. IGRA requires that Tribal gaming ordinances provide ''an adequate system which ensures that background investigations are conducted on the primary management officials and key employees of the gaming enterprise and (ii) includes—(I) [T]ribal licenses for primary management officials and key employees of the gaming enterprise . . .; (II) a standard whereby any person whose prior activities, criminal record, if any, or reputation, habits and associations pose a threat to the public interest or to the effective regulation of gaming, or create or enhance the dangers of unsuitable, unfair, or illegal practices and methods and activities in the conduct of gaming shall not be eligible for employment; and (III) notification by the Indian Tribe to the Commission of the results of such background check before the issuance of any of such licenses.''

The Commission first defined ''key employee'' and ''primary management official'' in April of 1992 (57 FR 123802–01). As mandated by IGRA, applicants for key employee and primary management official positions are subject to a background investigation as a condition of licensure. In 2009, the Commission expanded these definitions to permit Tribes to designate other persons as key employees or primary management officials (74 FR 36926). The U.S. Department of Justice, Federal Bureau of Investigation (FBI) took issue with this expansion, denying the processing of criminal history record information (CHRI) for the expanded positions' background investigations. This proposed rule rectifies that issue in part 502, limiting Tribal designations to ''[a]ny other employee of the gaming enterprise designated by the Tribe as a key employee'' and ''[a]ny other employed management official of the gaming enterprise designated by the Tribe as a primary management official.''

Background investigation and licensing regulations for key employees and primary management officials were initially issued by the Commission in January of 1993 (58 FR 5802–01) in parts 556 and 558, respectively. The Commission updated these regulations in 2013 to streamline the submission of documents; to ensure that two notifications are submitted to the Commission in compliance with IGRA; and to clarify the regulations regarding the issuance of temporary and permanent gaming licenses (78 FR 5276–01). As for part 556, this proposed rule incorporates the Gaming Enterprise definition, as needed, and modernizes the licensing application and background investigation retention requirements. And for part 558, the proposed rule emphasizes primary management official and key employee licensing rather than their employment; adds notification requirements for licensing revocation decisions; details the retention requirements of information and documentation related to key employees and primary management officials after their

employment ceases; and updates the vesting of a right to a hearing to include the requirements of Tribal law and policy.

B. Development of the Rule

On, June 9, 2021, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the key employee and primary management definitions and the backgrounding and licensing regulations. Prior to consultation, the Commission released proposed discussion drafts of the regulations for review. The proposed amendments to these regulations were intended to: address FBI's concerns regarding the key employee and primary management official definitions; include gaming operation employees with unescorted access to secured areas as key employees; combine certain subsections of the key employee definition; add general managers and similar positions to the primary management official definition; and update licensing application and background investigation retention requirements. The Commission held two virtual consultation sessions in July of 2021 to receive Tribal input on the possible changes.

The Commission reviewed all comments received as part of the consultation process. Several comments were concerned that defining a key employee as a ''Custodian of gambling device or system records'' would make TGRA personnel key employees. To address this concern, the Commission is proposing to limit the definition to persons who perform that function ''for the gaming operation.'' It is not the Commission's intent to capture TGRA employees or non-gaming operation personnel in the definition. A similar comment sought clarification as to whether ''[a]ny person authorized by the gaming operation for unescorted access to secured areas'' includes TGRA personnel. Again, it does not as in most cases the TGRA, not the gaming operation, authorizes TGRA personnel's access to restricted areas. However, under provision § 502.14(d)—''[a]ny other employee of the gaming enterprise designated by the Tribe as a key employee''—A Tribe may, at its discretion, designate TGRA personnel as key employees through its gaming ordinance, since the ''Gaming Enterprise'' definition includes ''the entities through which a Tribe conducts, regulates, and secures its gaming . . . .'' Likewise, if it so chooses, a Tribe may deem TGRA supervisory personnel as primary management officials under § 502.19(e)—''[a]ny other employed management official of the gaming enterprise designated by the Tribe as a primary management official.'' The intent of both proposed provisions is to provide maximum flexibility to Tribes.

II. Regulatory Matters

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget as required by 44 U.S.C. 3501, *et seq.,* and assigned OMB Control Number 3141–0003.

Tribal Consultation

The National Indian Gaming Commission is committed to fulfilling its Tribal consultation obligations—whether directed by statute or administrative action such as Executive Order (E.O.) 13175 (Consultation and Coordination with Indian Tribal Governments)—by adhering to the consultation framework described in its Consultation Policy published July 15, 2013. The NIGC's consultation policy specifies that it will consult with Tribes on Commission Action with Tribal Implications, which is defined as: Any Commission regulation, rulemaking, policy, guidance, legislative proposal, or operational activity that may have a substantial direct effect on an Indian Tribe on matters including, but not limited to the ability of an Indian Tribe to regulate its Indian gaming; an Indian Tribe's formal relationship with the Commission; or the consideration of the Commission's trust responsibilities to Indian Tribes.

Pursuant to this policy, on June 9, 2021, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the key employee and primary management official regulatory definitions as well as the background and licensing regulations. Consultations with Tribes were held on July 27 and 28, 2021.

List of Subjects in 25 CFR Parts 502, 556, and 558

Gambling, Indian lands.

Therefore, for reasons stated in the preamble, 25 CFR parts 502, 556, and 558 are amended as follows:

PART 502—DEFINITIONS

■ 1. The authority citation for part 502 continues to read as follows:

Authority: 25 U.S.C. 2701 *et seq.*

■ 2. Revise § 502.14 to read as follows:

§ 502.14 Key employee.

Key employee means:

(a) Any person who performs one or more of the following functions for the gaming operation:

(1) Bingo caller;

(2) Counting room supervisor;

(3) Chief of security;

(4) Floor manager;

(5) Pit boss;

(6) Dealer;

(7) Croupier;

(8) Approver of credit;

(9) Custodian of gaming systems as defined in 25 CFR 547.2 and similar class III systems, gaming cash or gaming cash equivalents, or gaming system records;

(10) Custodian of surveillance systems or surveillance system records.

(b) Any person authorized by the gaming operation for unescorted access to restricted areas designated as restricted areas by the TGRA;

(c) If not otherwise licensed as a key employee or primary management official, the four persons most highly compensated persons by the gaming operation.

(d) Any other employee of the gaming enterprise designated by the Tribe as a key employee in its gaming ordinance.

■ 3. Revise § 502.19 to read as follows:

§ 502.19 Primary management official.

Primary management official means:

(a) Any person having management responsibility for a management contract;

(b) Any person who has authority:

(1) To hire and fire employees of the gaming operation; or

(2) To establish policy for the gaming operation; or

(3) To supervise a key employee of the gaming operation.

(c) The chief financial officer or a position with duties similar to a chief financial officer.

(d) The general manager or a position with duties similar to a general manager.

(e) Any other employed management official of the gaming enterprise designated by the Tribe as a primary management official in its gaming ordinance.

■ 4. Add §§ 502.25 and 502.26 to read as follows:

§ 502.25 Gaming Enterprise.

Gaming Enterprise means the entities through which a Tribe conducts, regulates, and secures gaming on Indian lands within such Tribe's jurisdiction pursuant to the Indian Gaming Regulatory Act.

§ 502.26 Tribal Gaming Regulatory Authority (TGRA).

Tribal Gaming Regulatory Authority (TGRA) means the governmental entity authorized by Tribal law to regulate gaming conducted pursuant to the Indian Gaming Regulatory Act.

PART 556—BACKGROUND INVESTIGATIONS FOR PRIMARY MANAGEMENT OFFICIALS AND KEY EMPLOYEES

■ 5. The authority citation for part 556 is revised to read as follows:

Authority: 25 U.S.C. 2706, 2710.

■ 6. Amend § 556.4 by revising the first sentence of the introductory text to read as follows:

§ 556.4 Background investigations.

A Tribe shall perform a background investigation for each primary management official and for each key employee of the gaming enterprise.

* * *

* * * * *

■ 7. Amend § 556.6 by revising the first sentence of paragraph (a) to read as follows:

§ 556.6 Report to the Commission.

(a) When a Tribe licenses a primary management official or a key employee, the Tribe shall maintain the information listed under § 556.4(a)(1) through (14).

* * *

* * * * *

■ 8. Revise § 556.8 to read as follows:

§ 556.8 Compliance with this part.

All Tribal gaming ordinances and ordinance amendments approved by the Chair prior to [EFFECTIVE DATE OF FINAL RULE] do not need to be amended to comply with this part. All future ordinance submissions, however, must comply.

PART 558—GAMING LICENSES FOR KEY EMPLOYEES AND PRIMARY MANAGEMENT OFFICIALS

■ 9. The authority citation for part 558 continues to read as follows:

Authority: 25 U.S.C. 2706, 2710, 2712.

■ 10. Revise § 558.3 to read as follows:

§ 558.3 Notification to NIGC of license decisions and retention obligations.

(a) After a Tribe has provided a notice of results of the background check to the Commission, a Tribe may license a primary management official or key employee.

(b) Within 30 days after the issuance of the license, a Tribe shall notify the Commission of its issuance.

(c) A key employee or primary management official who does not have a license after ninety (90) days shall not be permitted to perform the duties, functions, and/or responsibilities of a key employee or primary management official until so licensed.

(d) If a Tribe does not license an applicant—

(1) The Tribe shall notify the Commission; and

(2) Shall forward copies of its eligibility determination and notice of results, under § 556.6(b)(2) of this chapter, to the Commission for inclusion in the Indian Gaming Individuals Record System.

(e) If a Tribe revokes a key employee or primary management official's license—

(1) The Tribe shall notify the Commission; and

(2) Shall forward copies of its license revocation decision and a summary of the evidence it relied upon to the Commission for inclusion in the Indian Gaming Individuals Record System.

(f) A Tribe shall retain the following for inspection by the Chair or their designee for no less than three years from the date of termination of employment:

(1) The information listed under § 556.4(a)(1) through (14) of this chapter;

(2) Investigative reports, as defined in § 556.6(b) of this chapter;

(3) Eligibility determinations, as defined in § 556.5 of this chapter;

(4) Privacy Act notice, as defined in § 556.2 of this chapter; and

(5) False Statement notice, as defined in § 556.3 of this chapter.

■ 11. Revise § 558.4 to read as follows:

§ 558.4 Notice of information impacting eligibility and licensee's right to a hearing.

(a) If, after the issuance of a gaming license pursuant to § 558.3, the Commission receives reliable information indicating that a key employee or a primary management official is not eligible for a license under § 556.5 of this chapter, the Commission shall notify the issuing Tribe of the information.

(b) Upon receipt of such notification under paragraph (a) of this section, a Tribe shall immediately suspend the license and shall provide the licensee with written notice of suspension and proposed revocation.

(c) A Tribe shall notify the licensee of a time and a place for a hearing on the proposed revocation of a license.

(d) The right to a revocation hearing shall vest upon receipt of a license or at such earlier time as is determined by Tribal law, regulation, and/or policy.

(e) After a revocation hearing, a Tribe shall decide to revoke or to reinstate a gaming license. A Tribe shall notify the Commission of its decision within 45 days of receiving notification from the Commission pursuant to paragraph (a) of this section.

■ 12. Revise § 558.6 to read as follows:

§ 558.6 Compliance with this part.

All Tribal gaming ordinances and ordinance amendments that have been approved by the Chair prior to [EFFECTIVE DATE OF FINAL RULE] do not need to be amended to comply with this section. All future ordinance submissions, however, must comply.

Dated: August 2, 2022.

E. Sequoyah Simermeyer,

Chairman.

Jeannie Hovland,

Vice Chair.

[FR Doc. 2022–16977 Filed 8–9–22; 8:45 am]

BILLING CODE 7565–01–M

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 585

RIN 3141–AA75

Appeals to the Commission

AGENCY: National Indian Gaming Commission, Department of the Interior.

ACTION: Proposed rule.

SUMMARY: The National Indian Gaming Commission proposes to amend its regulations to add a settlement process for appeals proceedings on written submissions to the Commission.

DATES: Written comments on this proposed rule must be received on or before September 9, 2022.

ADDRESSES: You may submit comments by any one of the following methods, however, please note that comments sent by electronic mail are strongly encouraged.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email comments to: information@nigc.gov.*
- *Mail comments to:* National Indian Gaming Commission, 1849 C Street NW, MS 1621, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Michael Hoenig at (202) 420–9241 (this number is not toll free).

SUPPLEMENTARY INFORMATION:

I. Background and Development of the Rule

A. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (''NIGC'' or ''Commission'') and set out a comprehensive framework for the regulation of gaming on Indian lands. IGRA, in several instances, requires that the Commission provide an opportunity for a hearing before it on: proposed fines, temporary closure orders, and removals of a certificate of self-regulation. Also through regulatory action, the Commission has afforded appeals before it for: notice of violations, modified and voided management contracts, and notices of late fees and late fee assessments. As to all these areas, part 585 of NIGC regulations offers appeals to the Commission on written submissions.

The Commission comprehensively updated the appeals regulations in 2012, consolidating them in one subchapter. (77 FR 58941–01). This proposed rule augments the appeals regulations by inserting a comprehensive settlement procedure for appeals under part 585, rectifying its absence in the current regulations.

B. Development of the Rule

On June 9, 2021, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the appeals regulations in part 585. Prior to consultation, the Commission sent another Notice of Consultation, dated September 13, 2021, and released a proposed discussion draft of the regulations for review. The proposed amendments to these regulations were intended to solicit Tribes' views on: (1) the Commission inviting, directing or granting leave to the Chair to file or respond to motions and (2) supplying a settlement procedure for appeals to the Commission on written submissions. The Commission held three virtual consultation sessions in September and October of 2021 to receive Tribal input on the possible changes. The Commission reviewed all comments received as part of the consultation process.

Commenters at the consultation phase requested the addition of language to the settlement procedures specifying that ''the NIGC will consider any and all such requests to enter into settlement negotiations in good faith.'' The Commission declines to add this language. It is unclear whether this comment is directed to the full Commission, who will decide whether to grant a stay of proceedings for the purposes of settlement negotiations between the Chair and the other party, or whether this comment is directed at the Chair. In any event, in the context of agency adjudications, the U.S. Supreme Court found that agency members are presumed to act in good faith, with honesty and integrity. *See Withrow* v. *Larkin,* 421 U.S. 35, 47 (1975). Therefore, the addition is unnecessary.

Additionally, based on comments received, the Commission omitted the proposed change permitting the Chair to respond to motions. Instead, the Commission proposes to limit the motions that may be filed in proceedings before the Commission to those listed in the regulation and prohibit the Chair from responding.

II. Regulatory Matters

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget as required by 44 U.S.C. 3501, *et seq.,* and assigned OMB Control Number 3141–0003.

Tribal Consultation

The National Indian Gaming Commission is committed to fulfilling its Tribal consultation obligations—whether directed by statute or administrative action such as Executive Order (E.O.) 13175 (Consultation and Coordination with Indian Tribal Governments)—by adhering to the consultation framework described in its Consultation Policy published July 15, 2013. The NIGC's consultation policy specifies that it will consult with Tribes on Commission Action with Tribal Implications, which is defined as: Any Commission regulation, rulemaking, policy, guidance, legislative proposal, or operational activity that may have a substantial direct effect on an Indian Tribe on matters including, but not limited to the ability of an Indian Tribe to regulate its Indian gaming; an Indian Tribe's formal relationship with the Commission; or the consideration of the Commission's trust responsibilities to Indian Tribes.

Pursuant to this policy, on June 9 and September 13, 2021, the National Indian Gaming Commission sent Notices of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the appeals regulations. The Commission held three virtual consultation sessions in September and October of 2021 to receive Tribal input on the possible changes.

List of Subjects in 25 CFR Part 585

Administrative practice and procedure, Appeals gambling, Indian-lands, Reporting and recordkeeping requirements.

Therefore, for reasons stated in the preamble, 25 CFR part 585 is amended as follows:

PART 585—APPEALS TO THE COMMISSION ON WRITTEN SUBMISSIONS OF NOTICES OF VIOLATION, PROPOSED CIVIL FINE ASSESSMENTS, ORDERS OF TEMPORARY CLOSURE, THE CHAIR'S DECISIONS TO VOID OR MODIFY MANAGEMENT CONTRACTS, THE COMMISSION'S PROPOSALS TO REMOVE A CERTIFICATE OF SELF–REGULATION, AND NOTICES OF LATE FEES AND LATE FEE ASSESSMENTS

■ 1. The authority citation for part 585 continues to read as follows:

Authority: 25 U.S.C. 2706, 2710, 2711, 2713, 2715, 2717.

■ 2. Revise § 585.4 to read as follows:

§ 585.4 Are motions permitted?

(a) Only motions for extension of time under § 580.4(f) of this subchapter, motions to supplement the record under § 581.5 of this subchapter, motions to intervene under § 585.5, and motions for reconsideration under § 581.6 of this subchapter, are permitted.

(b) The Chair shall not, either individually or through counsel, respond to motions.

■ 3. Add § 585.8 to read as follows:

§ 585.8 What is the process for pursuing settlement in an appeal to the Commission?

(a) *General.* At any time after the commencement of a proceeding, but before the date scheduled for the Commission to issue a final decision under § 585.7, the parties may jointly move to stay the proceeding for a reasonable time to permit negotiation of a settlement or an agreement disposing of the whole or any part of the proceeding.

(b) *Content.* Any agreement disposing of the whole or any part of a proceeding shall also provide:

(1) A waiver of any further proceedings before the Commission regarding the specific matter(s) settled under the agreement; and

(2) That the agreement shall constitute dismissal of the appeal of the specific matter(s) settled, a final order of the Commission, and final agency action.

(c) *Submission.* Before the expiration of the time granted for negotiations, the parties or their authorized representatives may:

(1) Notify the Commission that the parties have reached a full or partial settlement and have agreed to dismissal of all or part of the action, subject to compliance with the terms of the settlement agreement; or

(2) Inform the Commission that an agreement cannot be reached.

(d) *Disposition.* If the parties enter into a full or partial settlement agreement, it shall constitute: full or partial dismissal of the appeal, as applicable; a final order of the Commission; and final agency action.

Dated: August 2, 2022.

E. Sequoyah Simermeyer,

Chairman.

Jeannie Hovland,

Vice Chair.

[FR Doc. 2022–16976 Filed 8–9–22; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

RIN 0648–BI18

Fisheries of the Northeastern United States; Amendment 20 to the Atlantic Surfclam and Ocean Quahog Fishery Management Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of proposed fishery management plan amendment; request for comments.

SUMMARY: NMFS announces that the Mid-Atlantic Fishery Management Council has submitted Amendment 20 to the Atlantic Surfclam and Ocean Quahog Fishery Management Plan for review and approval by the Secretary of Commerce. We are requesting comments from the public on the amendment. Amendment 20, also known as the Excessive Shares Amendment, would establish limits to the amount of surfclam or ocean quahog individual transferable quota share or annual allocation in the form of cage tags that an individual or their family members could hold.

DATES: Comments must be received on or before October 11, 2022.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2020–0112, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2020–0112 in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope: ''Comments on Surfclam/Ocean Quahog Excessive Shares Amendment.''

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of Amendment 20, including the draft Environmental Assessment (EA), are available on request from the Mid-Atlantic Fishery Management Council, 800 North State Street, Suite 201, Dover, DE 19901. These documents are also accessible via the internet at *https://www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Douglas Potts, Fishery Policy Analyst, 978–281–9341.

SUPPLEMENTARY INFORMATION: We are soliciting public comments on Amendment 20, also known as the Excessive Shares Amendment, and its incorporated documents through the end of the comment period stated in this notice of availability. We will soon publish a proposed rule that would implement the amendment's management measures in the **Federal Register** for public comment, allowing for NMFS's evaluation of the proposed rule under the procedures of the Magnuson-Stevens Fishery Conservation and Management Act. Public comments on the proposed rule must be received by the end of the comment period provided in this notice of availability to be considered in the approval/disapproval decision on the amendment. All comments received by October 11, 2022, whether specifically directed to the amendment or the proposed rule will be considered in the approval/disapproval decision on the amendment. To be considered, comments must be received by close of business on the last day of the comment period. Comments received after that date will not be considered in the decision to approve or disapprove Amendment 20, including those

postmarked or otherwise transmitted by the last day of the comment period.

The Mid-Atlantic Fishery Management Council developed this amendment to limit the amount of surfclam or ocean quahog individual transferable quota (ITQ) share or annual allocation in the form of cage tags that an individual or their family members could hold. The Amendment would prohibit an ITQ shareholder, including business owners and their immediate family members, from acquiring ownership of more than 35 percent of the surfclam quota or 40 percent of the ocean quahog quota. A separate, higher cap would be established for the maximum amount of available cage tags that an ITQ permit holder may acquire through leasing or other transactions during the course of an individual fishing year of 65 percent for surfclam tags and 70 percent for ocean quahog tags.

Additional details of the proposed measures are available in the amendment document and the proposed rule.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: August 5, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–17179 Filed 8–9–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 87, No. 153
Wednesday, August 10, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2021–0066]

Addition of the Kingdom of Lesotho, the Republic of Benin, and the Republic of Botswana to the List of Regions Affected With Highly Pathogenic Avian Influenza

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we added the Kingdom of Lesotho, the Republic of Benin, and the Republic of Botswana to the list of regions that the Animal and Plant Health Inspection Service considers to be affected by highly pathogenic avian influenza (HPAI). These actions follow our imposition of HPAI-related restrictions on avian commodities originating from or transiting the Kingdom of Lesotho, the Republic of Benin, and the Republic of Botswana, as a result of the confirmation of HPAI in the Kingdom of Lesotho, the Republic of Benin, and the Republic of Botswana.

DATES: The Kingdom of Lesotho, the Republic of Benin, and the Republic of Botswana were added to the list of regions APHIS considers to be affected with HPAI, effective respectively on June 8, 2021; August 26, 2021; and September 10, 2021.

FOR FURTHER INFORMATION CONTACT: For further information regarding HPAI in the Kingdom of Lesotho and the Republic of Benin, contact Dr. John Grabau, APHIS Veterinary Services, Regionalization Evaluation Services, Strategy and Policy, 920 Main Campus Drive, Venture II, Raleigh, NC 27606; phone: (919) 855–7738; email: *AskRegionalization@usda.gov.* For further information regarding HPAI in the Republic of Botswana, contact Dr. C. Aaron Monroy, APHIS Veterinary Services, Regionalization Evaluation Services, Strategy and Policy, 920 Main Campus Drive, Venture II, Raleigh, NC 27606; phone: (919) 855–7207; email: *AskRegionalization@usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including Newcastle disease and highly pathogenic avian influenza (HPAI). The regulations prohibit or restrict the importation of live poultry, poultry meat, and other poultry products from regions where these diseases are considered to exist.

Section 94.6 of the regulations contains requirements governing the importation into the United States of carcasses, meat, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds from regions of the world where HPAI exists or is reasonably believed to exist. HPAI is an extremely infectious and potentially fatal form of avian influenza in birds and poultry that, once established, can spread rapidly from flock to flock. The Animal and Plant Health Inspection Service (APHIS) maintains a list of restricted regions it considers affected with HPAI of any subtype on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.*

APHIS receives notice of HPAI outbreaks from veterinary officials of the exporting country, from the World Organization for Animal Health (WOAH),[1] or from other sources the Administrator determines to be reliable.

On May 31, 2021, the veterinary authorities of the Kingdom of Lesotho reported to the WOAH an HPAI occurrence in that country. On June 8, 2021, after confirming that the HPAI occurred in commercial birds or poultry, APHIS added the Kingdom of Lesotho to the list of regions where HPAI exists. On that same day, APHIS issued an import alert notifying stakeholders that APHIS imposed restrictions on the importation of poultry, commercial birds, other types of birds (research, performing), ratites, any avian hatching eggs, unprocessed avian products and byproducts, and certain fresh poultry products from the Kingdom of Lesotho to mitigate risk of HPAI introduction into the United States.

On August 20, 2021, the veterinary authorities of the Republic of Benin reported to the WOAH an HPAI occurrence in that country. On August 26, 2021, after confirming that the HPAI occurred in commercial birds or poultry, APHIS added the Republic of Benin to the list of regions where HPAI exists. On that same day, APHIS issued an import alert notifying stakeholders that APHIS imposed restrictions on the importation of poultry, commercial birds, other types of birds (research, performing), ratites, any avian hatching eggs, unprocessed avian products and byproducts, and certain fresh poultry products from the Republic of Benin to mitigate risk of HPAI introduction into the United States.

On September 6, 2021, the veterinary authorities of the Republic of Botswana reported to the WOAH an HPAI occurrence in that country. On September 10, 2021, after confirming that the HPAI occurred in commercial birds or poultry, APHIS added the Republic of Botswana to the list of regions where HPAI exists. On that same day, APHIS issued an import alert notifying stakeholders that APHIS imposed restrictions on the importation of poultry, commercial birds, other types of birds (research, performing), ratites, any avian hatching eggs, unprocessed avian products and byproducts, and certain fresh poultry products from the Republic of Botswana to mitigate risk of HPAI introduction into the United States.

With the publication of this notice, we are informing the public that we added: The Kingdom of Lesotho to the list of regions APHIS considers affected with HPAI of any subtype, effective June 8, 2021; the Republic of Benin to the list of regions APHIS considers affected with HPAI of any subtype, effective August 26, 2021; and the Republic of Botswana to the list of regions APHIS considers affected with HPAI of any subtype, effective September 10, 2021.

[1] The World Organization for Animal Health internationally follows a British English spelling of ''organisation'' in its name; it was formerly the Office International des Epizooties, or OIE, but on May 28, 2022, the Organization announced that the acronym was changed from OIE to WOAH.

This notice serves as an official record and public notification of these actions.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this action as not a major rule, as defined by 5 U.S.C. 804(2).

Authority: 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 4th day of August 2022.

Anthony Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2022–17192 Filed 8–9–22; 8:45 am]

BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of a Public Meeting of the Maine Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of a public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that the Maine State Advisory Committee to the Commission will hold a virtual meeting for project planning on Thursday, September 8, 2022, at 12:00 p.m. (ET).

DATES: Thursday, September 8, 2022, at 12:00 p.m. (ET).

Public Web Conference Registration Link (video and audio): https://tinyurl.com/2p8uuzvu; password, if needed: USCCR–ME.

If Joining by Phone Only, Dial: 1–551–285–1373; Meeting ID: 161 025 9350#.

FOR FURTHER INFORMATION CONTACT: Liliana Schiller at *lschiller@usccr.gov* or 312–353–8311.

SUPPLEMENTARY INFORMATION: These meetings are available to the public through the WebEx link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing. may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the call-in number found through registering at the web link provided for these meetings.

Members of the public are entitled to make comments during the open period at the end of the meetings. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 539–8246. Records and documents discussed during the meetings will be available for public viewing as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda

Thursday, September 8, 2022, at 12 p.m. ET

I. Welcome & Roll Call
II. Approval of Minutes: July 18, 2022
III. Administrative Announcements
IV. Standing Meetings: 2nd Thursdays, From August thru December 2022; 12 p.m. ET
IV. Discussion: Project Proposal & Next Steps
  a. Update on Proposal
  b. Date of Briefing #1: October 20, 2022, Thursday; 12:00 p.m. ET
  c. Planning for Briefings
  d. Monday.com Panelist Recommendation Board
V. Public Comment
VI. Adjournment

Dated: August 5, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–17164 Filed 8–9–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Wyoming Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Wyoming Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Webex at 2:00 p.m. MT on Tuesday, September 27, 2022, to discuss the civil rights implications of housing discrimination in the state.

DATES: The meeting will take place on Tuesday, September 27, 2022, from 2:00 p.m.–3:30 p.m. MT.

Link To Join (Audio/Visual): https://tinyurl.com/tnh8dftp.

Telephone (Audio Only): Dial (800) 360–9505 USA Toll Free; Access Code: 2761 055 5065.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, DFO, at *kfajota@usccr.gov* or (434) 515–2395.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at (800) 877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *kfajota@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Wyoming Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at the above phone number.

Agenda

I. Welcome & Roll Call
II. Discussion: Housing Discrimination
III. Next Steps
IV. Public Comment
V. Adjournment

Dated: Friday, August 5, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–17165 Filed 8–9–22; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Amended Final Results of Antidumping Duty Administrative Review, 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is amending the final results of the administrative review of the antidumping duty (AD) order on crystalline silicon photovoltaic cells, whether or not assembled into modules, from the People's Republic of China (China) to correct a ministerial error. The period of review is December 1, 2019, through November 30, 2020.

DATES: Applicable August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Jeffrey Pedersen, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2769.

SUPPLEMENTARY INFORMATION:

Background

On June 28, 2022, Commerce published in the **Federal Register** the final results of the 2019–2020 administrative review of the AD order on crystalline silicon photovoltaic cells, whether or not assembled into modules, from China.[1] On July 5, 2022, the American Alliance for Solar Manufacturing (the petitioner) alleged that Commerce made a ministerial error in its calculations in the final results of review.[2] On July 11, 2022, Risen [3] rebutted the petitioner's ministerial error comments.[4]

Legal Framework

Pursuant to 19 CFR 351.224(e), Commerce will analyze any ministerial error comments received and, if appropriate, correct any ministerial error by amending the final results of review. According to section 751(h) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.224(f), a ministerial error is an error ''in addition, subtraction, or other arithmetic function, clerical errors resulting from inaccurate copying, duplication, or the like, and any other type of unintentional error which {Commerce} considers ministerial.''

Ministerial Error

After analyzing interested parties' comments, we have determined that we made a ministerial error in the final results by inadvertently using the incorrect average unit value for the Malaysian Harmonized Tariff Schedule subheading that we selcted to value the mandatory respondents' aluminum frames, profiles, keys, and extrusions. For details regarding the ministerial error, *see* the Ministerial Error Memorandum.[5]

Accordingly, we are amending our calculations of the mandatory respondents' dumping margins in the final results to reflect our correction of this error.[6] Because the dumping margins of the non-individually examined respondents to which we granted a separate rate are based on the weighted-average dumping margins that we calculated for the mandatory respondents, we also have amended the dumping margin that we assigned to these non-individually examined respondents.[7]

Amended Final Results

After correcting the ministerial error referenced above, we have determined that the following weighted-average dumping margins exist for the period of review, December 1, 2019 through November 30, 2020:

Producers/exporters	Weighted-average dumping margin (percent)
Jinko Solar Import and Export Co., Ltd./Jinko Solar Co., Ltd./JinkoSolar Technology (Haining) Co., Ltd./Yuhuan Jinko Solar Co., Ltd./Zhejiang Jinko Solar Co., Ltd./Jiangsu Jinko Tiansheng Solar Co., Ltd./JinkoSolar (Chuzhou) Co., Ltd./JinkoSolar (Yiwu) Co., Ltd./JinkoSolar (Shangrao) Co., Ltd	20.99
Risen Energy Co. Ltd./Risen (Wuhai) New Energy Co., Ltd./Zhejiang Twinsel Electronic Technology Co., Ltd./Risen (Luoyang) New Energy Co., Ltd./Jiujiang Shengzhao Xinye Technology Co., Ltd./Jiujiang Shengzhao Xinye Trade Co., Ltd./Ruichang Branch/Risen Energy (HongKong) Co., Ltd./Risen Energy (Changzhou) Co., Ltd./Risen Energy (YIWU) Co., Ltd	12.24
Review-Specific Rate Applicable to the Following Non-Examined Companies	
Anji DaSol Solar Energy Science & Technology Co., Ltd	14.79
BYD (Shangluo) Industrial Co., Ltd	14.79

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2019–2020,* 87 FR 38379 (June 28, 2022) (*Final Results*).

[2] *See* Petitioner's Letter ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Ministerial Error Allegation'' dated July 5, 2022.

[3] Risen refers to the single entity comprising the following companies: Risen Energy Co. Ltd.; Risen (Wuhai) New Energy Co., Ltd.; Zhejiang Twinsel Electronic Technology Co., Ltd.; Risen (Luoyang) New Energy Co., Ltd.; Jiujiang Shengzhao Xinye Technology Co., Ltd.; Jiujiang Shengzhao Xinye Trade Co., Ltd.; Ruichang Branch (Ruichang Branch), Risen Energy (HongKong) Co., Ltd.; Risen Energy (Changzhou) Co., Ltd.; and Risen Energy (YIWU) Co., Ltd.

[4] *See* Risen's Letter ''Crystalline Silicon Photovoltaic Cells from the People's Republic of China: Reply Ministerial Error Comments'' dated July 11, 2022.

[5] *See* Memorandum, ''2019–2020 Administrative Review of the Antidumping Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Ministerial Error Allegation in the Final Results,'' dated concurrently with this notice (Ministerial Error Memorandum).

[6] *See* Memorandum, ''Antidumping Duty Administrative Review of Certain Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Amended Final Results Analysis Memorandum—Jinko,'' dated concurrently with this notice; *see also* Memorandum, ''Antidumping Duty Administrative Review of Certain Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Amended Final Results Analysis Memorandum—Risen,'' dated concurrently with this notice.

[7] *See* Memorandum, ''2019–2020 Administrative Review of the Antidumping Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or not Assembled into Modules, from the People's Republic of China: Calculation of the Dumping Margin for Respondents Not Selected for Individual Examination for the Amended Final Results,'' dated concurrently with this notice.

Producers/exporters	Weighted-average dumping margin (percent)
Chint Solar (Zhejiang) Co., Ltd., Chint New Energy Technology (Haining) Co., Ltd., Chint Solar (Jiuquan) Co., Ltd., Chint Solar (Hong Kong) Company Limited	14.79
JA Solar Technology Yangzhou Co., Ltd	14.79
LONGi Solar Technology Co., Ltd	14.79
Shanghai JA Solar Technology Co., Ltd	14.79
Shenzhen Topray Solar Co., Ltd	14.79
Wuxi Suntech Power Co., Ltd	14.79
Wuxi Tianran Photovoltaic Co., Ltd	14.79
Xiamen Yiyusheng Solar Co., Ltd	14.79
Zhejiang Aiko Solar Energy Technology Co., Ltd	14.79

Disclosure

Pursuant to 19 CFR 351.224(b), within five days of the publication of this notice in the **Federal Register**, we will disclose to the parties to this proceeding, the calculations that we performed for these amended final results of review.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by the amended final results of review. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these amended final results of review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Where a mandatory respondent's weighted-average dumping margin is zero or *de minimis,* or where an importer-specific *ad valorem* or per-unit dumping margin is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[8] For U.S. entries that were not reported in a mandatory respondent's U.S. sales data, but that were entered under the case number of that respondent (*i.e.,* at the individually-examined exporter's cash deposit rate), Commerce will instruct CBP to liquidate such entries at the cash deposit rate for the China-wide entity (*i.e.,* 238.95 percent).

We calculated importer or customer-specific *ad valorem* assessment rates for the mandatory respondents by dividing the total amount of dumping duties for reviewed sales of subject merchandise imported by an importer, or for reviewed sales of subject merchandise to a customer, as appropriate, by the total sales value of those transactions.

For the companies not individually examined in this administrative review that qualified for a separate rate, the assessment rate will be equal to the weight average of the weighted-average dumping margins calculated for the mandatory respondents in these amended final results of review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice of the amended final results of review in the **Federal Register**, as provided by section 751(a)(2)(C) of the Act: (1) for the companies listed in the table above, the cash deposit rate will be equal to the weighted-average dumping margin listed for the company in the table; (2) for previously investigated or reviewed China and non-China exporters that are not under review in this segment of the proceeding that have a separate rate, the cash deposit rate will continue to be their existing exporter-specific rate; (3) for all China exporters of subject merchandise that do not have a separate rate, their cash deposit rate will be the cash deposit rate previously established for the China-wide entity, which is 238.95 percent; and (4) for all non-China exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be the cash deposit rate applicable to the China exporter that supplied the non-China exporter.

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(h) and 777(i)(1) of the Act, and 19 CFR 351.224(e).

Dated: August 3, 2022.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–17198 Filed 8–9–22; 8:45 am]

BILLING CODE 3510–DS–P

[8] *See* 19 CFR 351.106(c)(2).

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Manufacturing Extension Partnership Advisory Board

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Institute of Standards and Technology (NIST) announces that the Manufacturing Extension Partnership (MEP) Advisory Board will hold an open meeting on Tuesday, September 20, 2022.

DATES: The meeting will be held on Tuesday, September 20, 2022, from 12:30 p.m. to 6:00 p.m. Central time.

ADDRESSES: The meeting will be held at the InterContinental Chicago Magnificent Mile, 505 Michigan Avenue, Chicago, IL 60611. Please note admittance instructions in the **SUPPLEMENTARY INFORMATION** section below. Interested parties should be sure to check the NIST MEP Advisory Board website for the most up-to-date information at *http://www.nist.gov/mep/about/advisory-board.cfm.*

FOR FURTHER INFORMATION CONTACT: Cheryl L. Gendron, Hollings Manufacturing Extension Partnership Program, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, Maryland 20899–4800; telephone number (301) 975–2785; email: *cheryl.gendron@nist.gov.*

SUPPLEMENTARY INFORMATION: The MEP Advisory Board is authorized under 15 U.S.C 278k(m), in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. app. The Hollings Manufacturing Extension Partnership Program (Program) is a unique program consisting of Centers in all 50 states and Puerto Rico with partnerships at the federal, state and local levels. By statute, the MEP Advisory Board provides the NIST Director with: (1) advice on the activities, plans and policies of the Program; (2) assessments of the soundness of the plans and strategies of the Program; and (3) assessments of current performance against the plans of the Program.

Background information on the MEP Advisory Board is available at *http://www.nist.gov/mep/about/advisory-board.cfm.*

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. app., notice is hereby given that the MEP Advisory Board will hold an open meeting on Tuesday, September 20, 2022, from 12:30 p.m. to 6:00 p.m. Central time. The meeting agenda will include an update on the MEP programmatic operations, as well as provide guidance and advice on current activities related to both the current MEP National Network™ 2017–2022 Strategic Plan and upcoming MEP National Network 2023–2028 Strategic Plan. The agenda may change to accommodate Board business. The final agenda will be posted on the MEP Advisory Board website at *http://www.nist.gov/mep/about/advisory-board.cfm.* Individuals and representatives of organizations who would like to offer comments and suggestions related to the MEP Advisory Board's business are invited to request a place on the agenda. Approximately 15 minutes will be reserved for public comments at the end of the meeting. Speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received but is likely to be no more than three to five minutes each. Requests must be submitted by email to *cheryl.gendron@nist.gov* and must be received by September 14, 2022, to be considered. The exact time for public comments will be included in the final agenda that will be posted on the MEP Advisory Board website at *http://www.nist.gov/mep/about/advisory-board.cfm.* Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who wished to speak but could not be accommodated on the agenda or those who are/were unable to attend the meeting are invited to submit written statements electronically by email to *cheryl.gendron@nist.gov.*

Admittance Instructions: Anyone wishing to attend the MEP Advisory Board meeting must submit their name, organization, email address and phone number to Cheryl Gendron (*Cheryl.Gendron@nist.gov* or 301–975–2785) no later than Wednesday, September 14, 2022, 5:00 p.m. Eastern time.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2022–17136 Filed 8–9–22; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC114]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to In-Water Construction at Two Ferry Facilities on Bainbridge Island, Washington

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; proposed incidental harassment authorization (IHA); request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from the Washington State Department of Transportation Ferries Division (WSDOT) for authorization to take marine mammals incidental to two in-water construction projects on Bainbridge Island, Washington: the Bainbridge Island Ferry Terminal Overhead Loading Replacement Project and Eagle Harbor Maintenance Facility Slip F Improvement Project. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than September 9, 2022.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service and should be submitted via email to *ITP.Fowler@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at

www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Amy Fowler, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed incidental harassment authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On February 15, 2022, NMFS received a request from WSDOT for an IHA to take marine mammals incidental to the Bainbridge Island Ferry Terminal Overhead Loading Replacement Project (the Bainbridge Project) and Eagle Harbor Maintenance Facility Slip F Improvement Projects (the Eagle Harbor Project) in Bainbridge Island, Washington. The application was deemed adequate and complete on July 25, 2022. WSDOT's request is for take of 12 species of marine mammal by Level B harassment and, for a subset of these species (harbor seal (*Phoca vitulina*), harbor porpoise (*Phocoena phocoena*), and Dall's porpoise (*Phocoenoides dalli*)), Level A harassment. Neither WSDOT nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

The Washington State Department of Transportation (WSDOT) Ferries Division (WSF) operates and maintains 19 ferry terminals and one maintenance facility, all of which are located in either Puget Sound or the San Juan Islands. Two projects are proposed to be conducted: replacement of the Bainbridge Island Ferry Terminal overhead loading structure, and improvement of the Eagle Harbor Maintenance Facility Slip F. Both of the projects are located within Eagle Harbor on Bainbridge Island, Washington, would be completed within the same in-water work season, would have overlapping ensonified areas, and use the same datasets to estimate marine mammal takes. Therefore, WSDOT has submitted one application for a single IHA to cover both projects.

The purpose of the Bainbridge Project is to replace the seismically vulnerable timber trestle and fixed steel portions of the overhead loading structure at the Bainbridge Island Ferry Terminal. The purpose of the Eagle Harbor Project is to improve the maintenance efficiency of the facility. The facility has six vessel slips whose purpose is to maintain the Washington State Ferry (WSF) system's vessels.

Dates and Duration

Due to in-water work timing restrictions established by NMFS and the U.S. Army Corps of Engineers, construction in the projects area is limited each year from August 1 through February 15. Both the Bainbridge Project and the Eagle Harbor Project would be constructed during the August 1, 2022 to February 15, 2023 in-water work season. For the Bainbridge Project, in-water construction is expected to occur on up to 57 days (Table 1). For the Eagle Harbor Project, in-water construction is expected to occur on up to 31 days (Table 2).

Specific Geographic Region

Both projects are located within Eagle Harbor on Bainbridge Island, Washington, approximately 9 miles (mi; 14.5 kilometers (km)) west of Seattle, Washington. The Eagle Harbor Maintenance Facility is approximately ¼ mi (0.4 km) southwest of the Bainbridge Island Ferry Terminal. Eagle Harbor contains a mix of commercial docks, public marinas, private docks, and undeveloped waterfront properties. The harbor extends 2 mi (1.2 km) west from the mouth of the harbor, which is approximately 900 feet (ft; 274.3 meters (m)) wide and is bounded by Wing Point to the north and Bill Point to the south. A large underwater sand bar extends to the southeast from Wing Point. Water depths within Eagle Harbor range are up to 50 ft (15.2 m) but outside the harbor, water depths between Bainbridge Island and Seattle can be over 700 ft (213.4 m).

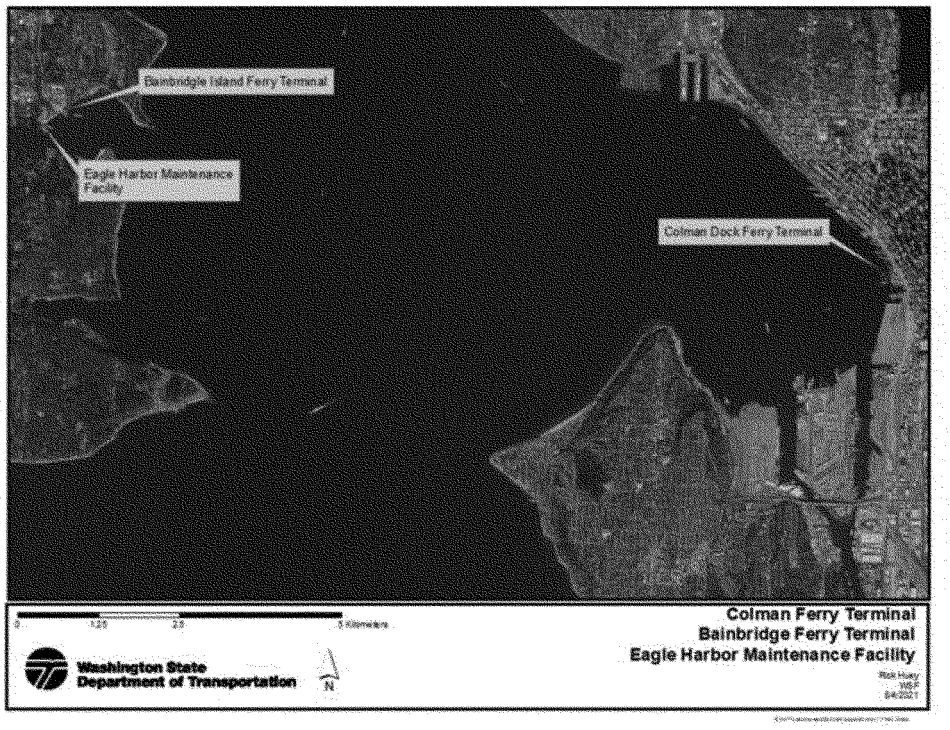

Figure 1. Location of Bainbridge Island Ferry Terminal and Eagle Harbor Maintenance Facility in Puget Sound

Detailed Description of Specific Activity

Bainbridge Project

The existing overhead loading fixed walkway at the Bainbridge Island Ferry Terminal consists of two major components: a timber trestle, constructed in 1972, which is approximately 345 ft (105.2 m) long and supported on timber batter piles; and a steel truss, constructed in 1988, which is approximately 78 ft (23.8 m) long and supported on a concrete shaft at each end. The walkway is elevated approximately 40 ft (12.2 m) above ground.

The proposed project elements for the Bainbridge Project include:

1. *Installation of temporary work platforms:* two temporary work platforms would support construction equipment. A total of 31 24-inch (in) steel pipe piles would support the structures, which would be installed first using a vibratory hammer to within 5 ft (1.5 m) of tip elevation, and then driven with an impact hammer to verify bearing capacity.

2. *Installation of temporary walkway:* a temporary walkway would be constructed to maintain overhead loading operations while the new walkway is constructed. This would allow the inshore portion of the existing walkway to be demolished so the new walkway can be constructed. The offshore portion of the existing walkway would remain to allow passenger loading until the new walkway is completed. The temporary walkway would be supported on four 24-inch diameter steel piles, which would be installed first using a vibratory hammer to within 5 ft (1.5 m) of tip elevation, and then driven with an impact hammer to verify bearing capacity.

3. *Installation of new permanent walkway:* the new walkway would be supported by 14 30-in and 12 36-in steel pipe piles, which would be installed first using a vibratory hammer to within 5 ft (1.5 m) of tip elevation, and then driven with an impact hammer to verify bearing capacity.

4. *Removal of existing overhead loading walkway:* the existing overhead loading walkway, including 76 creosote-treated 12-in timber piles and one 4.5 ft (1.4 m) diameter concrete drill shaft, would be removed. The piles would be removed using a vibratory hammer and the concrete drill shaft would be removed by cutting it with a saw at the mudline.

5. *Removal of temporary walkway and work platform:* after the new walkway is constructed, all piles associated with the temporary walkway and work platform would be removed with a vibratory hammer.

The construction schedule would be coordinated to allow work to occur around ferry boats that may be present in the Bainbridge Island Ferry Terminal slips.

TABLE 1—PROPOSED PILE DRIVING FOR THE BAINBRIDGE PROJECT

Project element	Pile size and type	Install or remove	Method	Number of piles	Duration per pile (minutes)	Piles per day	Duration (days)
Temporary work platform and temporary walkway.	24-in Steel	Install	Vibratory	39	30	4	10
			Impact	39	30	4	10
		Remove	Vibratory	39	30	4	10
New Overhead Loading Structure.	24-in Steel	Install	Vibratory	6	30	2	3
			Impact	6	30	2	3
	30-in Steel	Install	Vibratory	4	30	2	2
			Impact	4	30	2	2
	36-in Steel	Install	Vibratory	12	30	2	6
			Impact	12	30	2	6
Old Overhead Loading Structure Removal.	12-in Timber	Remove	Vibratory	76	15	15	5
Total Temporary Piles Installed and Removed				39			
Total Permanent Piles Installed				26			
Total Timber Piles Removed				76			
Total Duration (days)							57

Eagle Harbor Project

The last seven vessels built for the WSF fleet have evacuation slides on the passenger deck. These require the use of a vehicle drive-on slip to allow changing out these slides. Currently, only two of the six slips are vehicle drive-on slips. This results in delays when more than two vessels are undergoing maintenance. A new vehicle drive-on slip would be constructed to reduce maintenance delays, and provide more flexibility in accomplishing the various maintenance activities on the vessels that is crucial to making the WSF system as reliable as possible.

The proposed project elements for the Eagle Harbor Project include:

1. *Trestle and transfer span:* The vehicle transfer span is the link for vehicles to load and unload from the fixed trestle to the vehicle deck of the ferry vessel. At Eagle Harbor, the existing Slip F gangplank system would be replaced with a new pile supported trestle and a transfer span adjustable with a mechanical system. The new trestle would be approximately 15-ft (4.6 m) wide and 80 ft (24.4 m) long, and will be supported by nine 24-in steel pipe piles and two 36-in steel pipe piles which would each be installed first using a vibratory hammer to within 5 ft (1.5 m) of tip elevation, and then driven with an impact hammer to verify bearing capacity.

2. *Wingwalls and dolphins:* The existing pair of timber dolphins would be replaced with a new pair of steel wingwalls. Two new fixed pile dolphins would be constructed adjacent to the Trask Pier. The wingwalls design would consist of four 36-inch diameter steel reaction piles and two 36-inch diameter fender piles. Two fixed dolphins would be constructed adjacent to the Trask Pier to provide protection to the pier and mooring lines for tie-up. The dolphin design would consist of four 30-inch diameter steel reaction piles and one 36-inch diameter fender pile. Wingwall and dolphin piles would be installed using a vibratory hammer only.

3. *Removal of timber walkway, timber dolphins, and U-float:* the project would also include the removal of a currently existing timber walkway/trestle, four timber pile dolphins, and a U-float. The timber trestle removal includes 52 12-inch diameter timber piles, the four dolphins include a total of 134 12-inch diameter timber piles, and the U-float consists of four 18-inch diameter steel piles, all of which would be removed using a vibratory hammer.

TABLE 2—PROPOSED PILE DRIVING FOR THE EAGLE HARBOR PROJECT

Project element	Pile size and type	Install or remove	Method	Number of piles	Duration per pile (minutes)	Duration (hours)	Rate per day	Duration (days)
Timber Walkway Pile Removal.	12-in Timber	Remove	Vibratory	52	15	13	15	4
Timber Dolphin Removal.	12-in Timber	Remove	Vibratory	134	15	33.5	15	9
Temporary Relocated Float.	18-in Steel	Install	Vibratory	4	30	4	4	1
		Remove		4	30	3	4	1
U-Float Removal	18-in Steel	Remove	Vibratory	4	30	4	4	1
Trestle and Transfer Span.	24-in Steel	Install	Vibratory	9	30	4.5	4	3
			Impact	9	30	4.5	3	3
	36-inSteel	Install	Vibratory	2	30	1	4	1
			Impact	2	30	1	3	1
Wingwall	30-in Steel	Install	Vibratory	8	30	4	4	2
	36-in Steel	Install	Vibratory	4	30	2	4	1

TABLE 2—PROPOSED PILE DRIVING FOR THE EAGLE HARBOR PROJECT—Continued

Project element	Pile size and type	Install or remove	Method	Number of piles	Duration per pile (minutes)	Duration (hours)	Rate per day	Duration (days)
Intermediate Dolphin.	30-in Steel	Install	Vibratory	4	30	2	4	1
	36-in Steel	Install	Vibratory	1	30	5	4	1
Outer Dolphin	30-in Steel	Install	Vibratory	4	30	2	4	1
	36-in Steel	Install	Vibratory	2	30	1	4	1
Total Piles Removed				194				
Total Piles Installed				38				
Total Duration (days)								31

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, incorporated here by reference, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species).*

Table 3 lists all species or stocks for which take is expected and proposed to be authorized for this activity, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. Pacific and Alaska SARs. All values presented in Table 3 are the most recent available at the time of publication and are available in the 2020 SARs (Carretta *et al.,* 2021, Muto *et al.,* 2021) and draft 2021 SARs (available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*).

TABLE 3—SPECIES LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae:						
Gray whale	*Eschrichtius robustus*	Eastern N Pacific	-, -, N	26,960 (0.05, 25,849, 2016).	801	131
Family Balaenopteridae (rorquals):						
Minke whale	*Balaenoptera acutorostrata*	California/Oregon/Washington.	-, -, N	915 (0.792, 509, 2018)	4.1	≥0.59
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Long-Beaked Common Dolphin.	*Delphinus capensis*	California	-, -, N	83,379 (0.216, 69,636, 2018).	668	≥29.7
Bottlenose Dolphin	*Tursiops truncatus*	California Coastal	-, -, N	453 (0.06, 346, 2011)	2.7	≥2.0
Pacific White-Sided Dolphin.	*Lagenorhynchus obliquidens*	California/Oregon/Washington.	-, -, N	34,999 (0.222, 29,090, 2018).	279	7
Killer Whale	*Orcinus orca*	West Coast Transient	-, -, N	349 [4] (N/A, 349, 2018)	3.5	0.4
Family Phocoenidae (porpoises):						
Harbor Porpoise	*Phocoena phocoena*	Washington Inland Waters	-, -, N	11,233 (0.37, 8,308, 2015).	66	≥7.2
Dall's Porpoise	*Phocoenoides dalli*	California/Oregon/Washington.	-, -, N	16,498 (0.61, 10,286, 2019).	99	≥0.66

TABLE 3—SPECIES LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES—Continued

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions):						
California Sea Lion	*Zalophus californianus*	U.S.	-, -, N	257,606 (N/A, 233,515, 2014).	14,011	>320
Steller Sea Lion	*Eumetopias jubatus*	Eastern	-, -, N	43,201 [5] (see SAR, 43,201, 2017).	2,592	112
Family Phocidae (earless seals):						
Harbor Seal	*Phoca vitulina*	Washington Northern Inland Waters.	-, -, N	11,036 [6] (UNK, UNK, 1999).	UND	9.8
Northern Elephant Seal	*Mirounga angustirostris*	California Breeding	-, -, N	187,386 (N/A, 85,369, 2013).	5,122	13.7

[1] *ESA status:* Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance.

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual mortality/serious injury (M/SI) often cannot be determined precisely and is in some cases presented as a minimum value or range.

[4] Based on counts of individual animals identified from photo-identification catalogues. Surveys for abundance estimates of these stocks are conducted infrequently.

[5] Best estimate of pup and non-pup counts, which have not been corrected to account for animals at sea during abundance surveys.

[6] The abundance estimate for this stock is greater than eight years old and is therefore not considered current. PBR is considered undetermined for this stock, as there is no current minimum abundance estimate for use in calculation. We nevertheless present the most recent abundance estimates, as these represent the best available information for use in this document.

As indicated above, all 12 species (with 12 managed stocks) in Table 3 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. While humpback whales (*Megaptera novaeangliae*) and killer whales from the Southern Resident stock are known to occur in Puget Sound, in consideration of the proposed requirements described in the Proposed Mitigation and Proposed Monitoring and Reporting sections of this notice, WSDOT has determined that take of these species is unlikely to occur and has therefore not requested take of humpback whales or Southern Resident killer whales. NMFS has concurred with this determination and no take of these species is anticipated or proposed to be authorized.

Gray Whale

Gray whales generally spend the summer and fall in Arctic feeding grounds and winter to early spring in Mexican breeding areas. Between October and February, the species migrates south along the U.S. West Coast, returning north between February and July (Carretta *et al.,* 2021). A subpopulation of the Eastern North Pacific stock, referred to as the Pacific Coast Feeding Group (PCFG), remains along the Washington and Oregon coast to feed for extended periods while the rest of the stock continues along their migratory path (Calambokidis *et al.,* 2018). Occurrence of gray whales in Puget Sound has been steadily increasing in recent years and is generally highest between February and May. Most gray whales remain further north in Puget Sound, concentrating in the waters around Whidbey Island, but some venture south, including into Elliott Bay near WSDOT's proposed activities (Orca Network, 2021). During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a total of 4 gray whales were observed, with a maximum of 1 individual observed on a single day.

Biologically Important Areas (BIAs) for feeding gray whales along the coasts of Washington, Oregon, and California have been identified, including northern Puget Sound, Northwestern Washington, and Grays Harbor in Washington, Depoe Bay and Cape Blanco and Orford Reef in Oregon, and Point St. George in California; most of these areas are of importance from late spring through early fall (Calambokidis *et al.,* 2015). BIAs have also been identified for migrating gray whales along the entire coasts of Washington (including the inland waters of Puget Sound), Oregon, and California; although most whales travel within 10 km from shore, the BIAs were extended out to 47 km from the coastline (Calambokidis *et al.,* 2015).

On May 30, 2019, NMFS declared an unusual mortality event (UME) for gray whales after elevated numbers of strandings occurred along the U.S. west coast. As of January 7, 2022, a total of 502 stranded gray whales have been reported, including 256 in the United States (117 in Alaska, 56 in Washington, 12 in Oregon, and 71 in California), 225 in Mexico, and 21 in Canada. Full or partial necropsy examinations were conducted on a subset of the whales. Preliminary findings in several of the whales have shown evidence of emaciation. These findings are not consistent across all of the whales examined, so more research is needed. The UME is ongoing, and NMFS continues to investigate the cause(s). Additional information about the UME is available at *https://www.fisheries.noaa.gov/national/marine-life-distress/2019-2020-gray-whale-unusual-mortality-event-along-west-coast.*

Minke Whale

The International Whaling Commission (IWC) recognizes three stocks of minke whales in the North Pacific: The Sea of Japan/East China Sea, the rest of the western Pacific west of 180° N, and the remainder of the Pacific (Donovan 1991). Minke whales are relatively common in the Bering and Chukchi seas and in the Gulf of Alaska, but are not considered abundant in any other part of the eastern Pacific (Brueggeman *et al.,* 1990). In the far north, minke whales are thought to be migratory, but they are believed to be year-round residents in coastal waters off the west coast of the United States (Dorsey *et al.,* 1990).

Minke whales are reported in Washington inland waters year-round, although few are reported in the winter (*i.e.,* during the anticipated in-water work window for these projects;

Calambokidis and Baird 1994). They are relatively common in the San Juan Islands and Strait of Juan de Fuca (especially around several of the banks in both the central and eastern Strait), but are relatively rare in Puget Sound and the Orca Network has no sighting records of minke whales in the project areas. During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a single minke whale was observed.

Long-Beaked Common Dolphin

Long-beaked common dolphins are commonly found along the U.S. West Coast, from Baja California, Mexico (including the Gulf of California), northward to about central California (Carretta *et al.,* 2020). The Salish Sea is not considered part of their typical range (Carretta *et al.,* 2020), but there have been reports of long-beaked common dolphins in inland waters. Two individual common dolphins were observed in August and September of 2011 (Whale Museum, 2015). The first record of a pod of long-beaked common dolphins in this area came in the summer of 2016. Beginning on June 16, 2016 long-beaked common dolphins were observed near Victoria, B.C. Over the following weeks, a pod of 15 to 20 (including a calf) was observed in central and southern Puget Sound. They were positively identified as long-beaked common dolphins (Orca Network 2016). Two long-beaked common dolphins were observed by Washington State Department of Transportation (WSDOT) marine mammal monitors during construction at Washington State Ferries Multimodal Project at Colman Dock in Seattle during the 2017–18 construction window (WSDOT 2019).

Bottlenose Dolphin

Bottlenose dolphins are distributed worldwide from approximately 45° N to 45° S. Bottlenose dolphins inhabiting west coast U.S. waters are considered to be in either the California coastal stock, which ranges from Mexico to the San Francisco area within approximately 1 kilometer of shore, or the California/Oregon/Washington offshore stock, which is most commonly found along the California coast, northward to about the Oregon border. NMFS offshore surveys from 1991 to 2014 resulted in no sightings during study transects off the Oregon or Washington coasts (Carretta *et al.,* 2019). In September 2017, however, multiple sightings of a bottlenose dolphin throughout the Puget Sound and in Elliott Bay were reported to Cascadia Research Collective and Orca Network. One of the individuals was identified as belonging to the California coastal stock (Cascadia Research Collective, 2017). Bottlenose dolphins are considered rare in Puget Sound but occasional sightings have continued since the initial reports in 2017 (Orca Network, 2021). During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a total of 6 bottlenose dolphins were observed, with a maximum of 2 individuals observed on a single day.

Pacific White-Sided Dolphin

The Pacific white-sided dolphin is found in cool temperate waters of the North Pacific from the southern Gulf of California to Alaska. Across the North Pacific, it appears to have a relatively narrow distribution between 38° N and 47° N (Brownell *et al.,* 1999). In the eastern North Pacific Ocean, the Pacific white-sided dolphin is one of the most common cetacean species, occurring primarily in shelf and slope waters (Green *et al.,* 1993; Barlow 2003, 2010). It is known to occur close to shore in certain regions, including (seasonally) southern California (Brownell *et al.,* 1999). Results of aerial and shipboard surveys strongly suggest seasonal north-south movements of the species between California and Oregon/Washington; the movements apparently are related to oceanographic influences, particularly water temperature (Green *et al.,* 1993; Forney and Barlow 1998; Buchanan *et al.,* 2001). During winter, this species is most abundant in California slope and offshore areas; as northern waters begin to warm in the spring, it appears to move north to slope and offshore waters off Oregon/Washington (Green *et al.,* 1992, 1993; Forney 1994; Forney *et al.,* 1995; Buchanan *et al.,* 2001; Barlow 2003). The highest encounter rates off Oregon and Washington have been reported during March-May in slope and offshore waters (Green *et al.,* 1992). Large groups of Pacific white-sided dolphins have been observed in San Juan Channel (Orca Network 2012), north of Puget Sound, and may rarely occur in Central Puget Sound. During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a total of 2 Pacific white-sided dolphins were observed on one day of construction.

Killer Whale

There are three distinct ecotypes, or forms, of killer whales recognized in the north Pacific: resident, transient, and offshore. The three ecotypes differ morphologically, ecologically, behaviorally, and genetically. Resident killer whales exclusively prey upon fish, with a clear preference for salmon (Ford and Ellis 2006; Hanson *et al.,* 2010; Ford *et al.,* 2016), while transient killer whales exclusively prey upon marine mammals (Caretta *et al.,* 2019). Less is known about offshore killer whales, but they are believed to consume primarily fish, including several species of shark (Dahlheim *et al.,* 2008). Currently, there are eight killer whale stocks recognized in the U.S. Pacific (Carretta *et al.,* 2021; Muto *et al.,* 2021). Of those, individuals from the West Coast Transient stock may occur in the project areas and be taken incidental to WSDOT's proposed activities.

Within Puget Sound, transient killer whales primarily hunt pinnipeds and porpoises, though some groups will occasionally target larger whales. The West Coast Transient stock of killer whales occurs from California through southeast Alaska (Muto *et al.,* 2021). The seasonal movements of transients are largely unpredictable, although there is a tendency to investigate harbor seal haulouts off Vancouver Island more frequently during the pupping season in August and September (Baird 1994; Ford 2014). Transient killer whales have been observed in central Puget Sound in all months (Orca Network 2021). During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a total of 47 transient killer whales were observed, with a maximum of 20 individuals observed on a single day.

Harbor Porpoise

In the eastern North Pacific Ocean, harbor porpoise are found in coastal and inland waters from Point Barrow, along the Alaskan coast, and down the west coast of North America to Point Conception, California (Gaskin 1984). Harbor porpoise are known to occur year-round in the inland trans-boundary waters of Washington and British Columbia, Canada (Osborne *et al.,* 1988), and along the Oregon/Washington coast (Barlow 1988, Barlow *et al.,* 1988, Green *et al.,* 1992). There was a significant decline in harbor porpoise sightings within southern Puget Sound between the 1940s and 1990s but sightings have increased seasonally in the last 10 years (Carretta *et al.,* 2019). Annual winter aerial surveys conducted by the Washington Department of Fish and Wildlife from 1995 to 2015 revealed an increasing trend in harbor porpoise in Washington

inland waters, including the return of harbor porpoise to Puget Sound. The data suggest that harbor porpoise were already present in Juan de Fuca, Georgia Straits, and the San Juan Islands from the mid-1990s to mid-2000s, and then expanded into Puget Sound and Hood Canal from the mid-2000s to 2015, areas they had used historically but abandoned. Changes in fishery-related entanglement was suspected as the cause of their previous decline and more recent recovery, including a return to Puget Sound (Evenson *et al.,* 2016). Seasonal surveys conducted in spring, summer, and fall 2013–2015 in Puget Sound and Hood Canal documented substantial numbers of harbor porpoise in Puget Sound. Observed porpoise numbers were twice as high in spring as in fall or summer, indicating a seasonal shift in distribution of harbor porpoise (Smultea 2015). The reasons for the seasonal shift and for the increase in sightings is unknown. During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a total of 413 harbor porpoises were observed, with a maximum of 40 individuals observed on a single day.

Dall's Porpoise

Dall's porpoises are endemic to temperate waters of the North Pacific Ocean. Off the U.S. West Coast, they are commonly seen in shelf, slope, and offshore waters (Morejohn 1979). Sighting patterns from aerial and shipboard surveys conducted in California, Oregon, and Washington (Green *et al.,* 1992, 1993; Forney and Barlow 1998; Barlow 2016) suggest that north-south movement between these states occurs as oceanographic conditions change, both on seasonal and inter-annual time scales. Dall's porpoise are considered rare in Puget Sound. During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a total of 8 Dall's porpoises were observed, with a maximum of 5 individuals observed on a single day.

California Sea Lion

The California sea lion is the most frequently sighted pinniped found in Washington waters and uses haul-out sites along the outer coast, Strait of Juan de Fuca, and in Puget Sound. Haul-out sites are located on jetties, offshore rocks and islands, log booms, marina docks, and navigation buoys. This species also may be frequently seen resting in the water, rafted together in groups in Puget Sound. Only male California sea lions migrate into Pacific Northwest waters, with females remaining in waters near their breeding rookeries off the coast of California and Mexico. The California sea lion was considered rare in Washington waters prior to the 1950s. More recently, peak numbers of 3,000 to 5,000 animals move into the Salish Sea during the fall and remain until late spring, when most return to breeding rookeries in California and Mexico (Jeffries *et al.,* 2000).

California sea lions are often observed in the area of potential effects and are known to be comfortable and seemingly curious around human activities. The nearest documented California sea lion haulout is 2.3 mi (3.7 km) southeast of the project sites on Blakely Rocks. Jeffries *et al.* (2000) estimated less than 100 California sea lions occupy the Blakely Rocks haulout site. California sea lions are not commonly observed in Eagle Harbor but are regularly observed in Elliott Bay, especially around two navigational buoys near Alki Point, at the southwest edge of Elliott Bay. During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a maximum of 38 California sea lions were observed on a single day.

Steller Sea Lion

Steller sea lions range along the North Pacific Rim from northern Japan to California (Loughlin *et al.,* 1984). There are two separate stocks of Steller sea lions, the Eastern U.S. stock, which occurs east of Cape Suckling, Alaska (144° W), and the Western U.S. stock, which occurs west of that point. Only the Western stock of Steller sea lions, which is designated as the Western DPS of Steller sea lions, is listed as endangered under the ESA (78 FR 66139; November 4, 2013). Unlike the Western U.S. stock of Steller sea lions, there has been a sustained and robust increase in abundance of the Eastern U.S. stock throughout its breeding range. The eastern stock of Steller sea lions has historically bred on rookeries located in Southeast Alaska, British Columbia, Oregon, and California. However, within the last several years a new rookery has become established on the outer Washington coast (at the Carroll Island and Sea Lion Rock complex), with more than 100 pups born there in 2015 (Muto *et al.,* 2020).

Steller sea lions use haul-out locations in Puget Sound, and may occur at the same haul-outs as California sea lions, but are considered rare visitors to the waters around Bainbridge Island. Few Steller sea lions have been observed during monitoring of recent construction projects in the Seattle area; typically fewer than 5 total observations per year (*e.g.,* Anchor QEA 2018, 2019). During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a total of 100 Steller sea lions were observed, with a maximum of 10 Steller sea lions observed on a single day.

Harbor Seal

Harbor seals inhabit coastal and estuarine waters off Baja California, north along the western coasts of the continental U.S., British Columbia, and Southeast Alaska, west through the Gulf of Alaska and Aleutian Islands, and in the Bering Sea north to Cape Newenham and the Pribilof Islands (Carretta *et al.,* 2014). They haul out on rocks, reefs, beaches, and drifting glacial ice and feed in marine, estuarine, and occasionally fresh waters. Harbor seals generally are non-migratory, with local movements associated with such factors as tides, weather, season, food availability, and reproduction (Scheffer and Slipp 1944; Fisher 1952; Bigg 1969, 1981). Within U.S. west coast waters, five stocks of harbor seals are recognized: (1) Southern Puget Sound (south of the Tacoma Narrows Bridge); (2) Washington Northern Inland Waters (including Puget Sound north of the Tacoma Narrows Bridge, the San Juan Islands, and the Strait of Juan de Fuca); (3) Hood Canal; (4) Oregon/Washington Coast; and (5) California. Harbor seals in the project areas would be from the Washington Northern Inland Waters stock.

Harbor seals are the only pinniped species that occurs year-round and breeds in Washington waters (Jeffries *et al.,* 2000). Pupping seasons vary by geographic region, with pups born in coastal estuaries (Columbia River, Willapa Bay, and Grays Harbor) from mid-April through June; Olympic Peninsula coast from May through July; San Juan Islands and eastern bays of Puget Sound from June through August; southern Puget Sound from mid-July through September; and Hood Canal from August through January (Jeffries *et al.,* 2000). The most recent estimate for the Washington Northern Inland Waters Stock is 11,036 based on surveys conducted in 1999. There are no current estimates of abundance for this stock but the population is thought to be stable (Carretta *et al.,* 2014).

There is one documented harbor seal haulout area near Bainbridge Island at Blakely Rocks, approximately 2.3 mi (3.7 km) southeast of the project sites. The haulout, which is estimated at less

than 100 animals, consists of intertidal rocks and reef areas (Jefferies *et al.,* 2000). Harbor seals are a commonly observed marine mammal in the area of potential effects and are known to be comfortable and seemingly curious around human activities. Observations of harbor seals were reported during many recent construction projects along the Seattle waterfront. During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a maximum of 43 harbor seals were observed on a single day.

Northern Elephant Seal

Northern elephant seals breed and give birth in California (U.S.) and Baja California (Mexico), primarily on offshore islands (Stewart *et al.,* 1994), from December to March (NOAA 2015). Males migrate to the Gulf of Alaska and western Aleutian Islands along the continental shelf to feed on benthic prey, while females migrate to pelagic areas in the Gulf of Alaska and the central North Pacific Ocean to feed on pelagic prey (Le Boeuf *et al.,* 2000). Adults return to land between March and August to molt, with males returning later than females. Adults return to their feeding areas again between their spring/summer molting and their winter breeding seasons (Carretta *et al.,* 2015).

During 372 total days of construction at the Washington State Ferries Multimodal Project at Colman Dock in Seattle between 2017 and 2021, a single northern elephant seal was observed. Elephant seals are generally considered rare in Puget Sound. However, a female elephant seal has been reported hauled-out in Mutiny Bay on Whidbey Island periodically since 2010. She was observed alone for her first three visits to the area, but in March 2015, she was seen with a pup. Since then, she has produced two more pups, born in 2018 and 2020. Northern elephant seals generally give birth in January but this individual has repeatedly given birth in March. She typically returns to Mutiny Bay in April and May to molt. Her pups have also repeatedly returned to haul-out on nearby beaches (Orca Network 2020).

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, etc.). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 4.

TABLE 4—MARINE MAMMAL HEARING GROUPS (NMFS, 2018)

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The Estimated Take section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Acoustic effects on marine mammals during the specified activities can occur from impact pile driving and vibratory driving and removal. The effects of underwater noise from WSDOT's proposed activities have the potential to result in Level A or Level B harassment of marine mammals in the action areas.

Description of Sound Sources

The marine soundscape is comprised of both ambient and anthropogenic sounds. Ambient sound is defined as the all-encompassing sound in a given place and is usually a composite of sound from many sources both near and far (ANSI 1995). The sound level of an area is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* waves, wind, precipitation, earthquakes, ice, atmospheric sound), biological (*e.g.,*

sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (*e.g.,* vessels, dredging, aircraft, construction).

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 decibels (dB) from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from the specified activities may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

In-water construction activities associated with the projects would include impact and vibratory pile driving and removal. The sounds produced by these activities fall into one of two general sound types: impulsive and non-impulsive. Impulsive sounds (*e.g.,* explosions, sonic booms, impact pile driving) are typically transient, brief (less than 1 second), broadband, and consist of high peak sound pressure with rapid rise time and rapid decay (ANSI, 1986; NIOSH, 1998; NMFS, 2018). Non-impulsive sounds (*e.g.,* machinery operations such as drilling or dredging, vibratory pile driving, underwater chainsaws, and active sonar systems) can be broadband, narrowband or tonal, brief or prolonged (continuous or intermittent), and typically do not have the high peak sound pressure with raid rise/decay time that impulsive sounds do (ANSI 1995; NIOSH 1998; NMFS 2018). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward 1997 in Southall *et al.,* 2007).

Two types of hammers would be used on these projects, impact and vibratory. Impact hammers operate by repeatedly dropping and/or pushing a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is considered impulsive. Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the sediment. Vibratory hammers produce non-impulsive, continuous sounds. Vibratory hammering generally produces SPLs 10 to 20 dB lower than impact pile driving of the same-sized pile (Oestman *et al.,* 2009). Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson *et al.,* 2005).

The likely or possible impacts of WSDOT's proposed activities on marine mammals could be generated from both non-acoustic and acoustic stressors. Potential non-acoustic stressors include the physical presence of the equipment, vessels, and personnel; however, we expect that any animals that approach the project site(s) close enough to be harassed due to the presence of equipment or personnel would be within the Level B harassment zones from pile driving and would already be subject to harassment from the in-water activities. Therefore, any impacts to marine mammals are expected to primarily be acoustic in nature. Acoustic stressors are generated by heavy equipment operation during pile installation and removal (*i.e.,* impact and vibratory pile driving and removal).

Acoustic Impacts

The introduction of anthropogenic noise into the aquatic environment from pile driving equipment is the primary means by which marine mammals may be harassed from WSDOT's specified activities. In general, animals exposed to natural or anthropogenic sound may experience physical and psychological effects, ranging in magnitude from none to severe (Southall *et al.,* 2007). Generally, exposure to pile driving and removal and other construction noise has the potential to result in auditory threshold shifts and behavioral reactions (*e.g.,* avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior). Exposure to anthropogenic noise can also lead to non-observable physiological responses such as an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions such as communication and predator and prey detection. The effects of pile driving and demolition noise on marine mammals are dependent on several factors, including, but not limited to, sound type (*e.g.,* impulsive vs. non-impulsive), the species, age and sex class (*e.g.,* adult male vs. mother with calf), duration of exposure, the distance between the pile and the animal, received levels, behavior at time of exposure, and previous history with exposure (Wartzok *et al.,* 2004; Southall *et al.,* 2007). Here we discuss physical auditory effects (threshold shifts) followed by behavioral effects and potential impacts on habitat. No physiological effects other than PTS are anticipated or proposed to be authorized, and therefore are not discussed further.

NMFS defines a noise-induced threshold shift (TS) as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). The amount of threshold shift is customarily expressed in dB. A TS can be permanent or temporary. As described in NMFS (2018), there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.,* impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.,* spectral content), the hearing and vocalization frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.,* how animal uses sound within the frequency band of the signal; *e.g.,* Kastelein *et al.,* 2014), and the overlap between the animal and the source (*e.g.,* spatial, temporal, and spectral).

Permanent Threshold Shift (PTS)—NMFS defines PTS as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS 2018). Available data from humans and other terrestrial mammals indicate that a 40 dB threshold shift approximates PTS onset (see Ward *et al.,* 1958, 1959; Ward, 1960; Kryter *et al.,* 1966; Miller, 1974; Ahroon *et al.,* 1996; Henderson *et al.,* 2008). PTS levels for marine mammals are estimates, because there are limited empirical data measuring PTS in marine mammals (*e.g.,* Kastak *et al.,* 2008), largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing PTS are not typically pursued or authorized (NMFS, 2018).

Temporary Threshold Shift (TTS)—TTS is a temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a

previously established reference level (NMFS, 2018). Based on data from cetacean TTS measurements (see Southall *et al.,* 2007), a TTS of 6 dB is considered the minimum threshold shift clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Schlundt *et al.,* 2000; Finneran *et al.,* 2000, 2002). As described in Finneran (2016), marine mammal studies have shown the amount of TTS increases with cumulative sound exposure level (SEL_{cum}) in an accelerating fashion: At low exposures with lower SEL_{cum}, the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher SEL_{cum}, the growth curves become steeper and approach linear relationships with the noise SEL.

Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.,* 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin, beluga whale (*Delphinapterus leucas*), harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaeorientalis*)) and five species of pinnipeds exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band noise) in laboratory settings (Finneran, 2015). TTS was not observed in trained spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to impulsive noise at levels matching previous predictions of TTS onset (Reichmuth *et al.,* 2016). In general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). The potential for TTS from impact pile driving exists. After exposure to playbacks of impact pile driving sounds (rate 2,760 strikes/hour) in captivity, mean TTS increased from 0 dB after 15 minute exposure to 5 dB after 360 minute exposure; recovery occurred within 60 minutes (Kastelein *et al.,* 2016). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. No data are available on noise-induced hearing loss for mysticetes. Nonetheless, what we considered is the best available science. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall *et al.* (2007), Finneran and Jenkins (2012), Finneran (2015), and Table 5 in NMFS (2018).

WSDOT proposes to use impact pile driving to install some piles for these projects. There would likely be pauses in activities producing the sound (*e.g.,* impact pile driving) during each day. Given these pauses and the fact that many marine mammals are likely moving through the project areas and not remaining for extended periods of time, the potential for TS declines.

Behavioral Harassment—Exposure to noise from pile driving and removal also has the potential to behaviorally disturb marine mammals. Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005).

Disturbance may result in changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); or avoidance of areas where sound sources are located. Pinnipeds may increase their haul-out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006). Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2004; Southall *et al.,* 2007; Weilgart, 2007; Archer *et al.,* 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.,* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Please see Appendices B and C of Southall *et al.* (2007) for a review of studies involving marine mammal behavioral responses to sound.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.,* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

In 2016, the Alaska Department of Transportation and Public Facilities (ADOT&PF) documented observations of marine mammals during construction activities (*i.e.,* pile driving) at the Kodiak Ferry Dock (see 80 FR 60636, October 7, 2015). In the marine mammal monitoring report for that project (ABR 2016), 1,281 Steller sea lions were observed within the Level B disturbance zone during pile driving or drilling (*i.e.,* documented as Level B harassment take). Of these, 19 individuals demonstrated an alert behavior, 7 were fleeing, and 19 swam away from the

project site. All other animals (98 percent) were engaged in activities such as milling, foraging, or fighting and did not change their behavior. In addition, two sea lions approached within 20 m of active vibratory pile driving activities. Three harbor seals were observed within the disturbance zone during pile driving activities; none of them displayed disturbance behaviors. Fifteen killer whales and three harbor porpoise were also observed within the Level B harassment zone during pile driving. The killer whales were travelling or milling while all harbor porpoises were travelling. No signs of disturbance were noted for either of these species. Given the similarities in species, activities, and habitat (*e.g.,* cool-temperate waters, industrialized area), we expect similar behavioral responses from the same and similar species affected by WSDOT's specified activities. That is, disturbance, if any, is likely to be temporary and localized (*e.g.,* small area movements).

Stress responses—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Seyle 1950; Moberg 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg 1987; Blecha 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.,* 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker 2000; Romano *et al.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003), however distress is an unlikely result of these projects based on observations of marine mammals during previous, similar projects in the area.

Masking—Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.,* 1995). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* pile driving, shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions. Masking of natural sounds can result when human activities produce high levels of background sound at frequencies important to marine mammals. Conversely, if the background level of underwater sound is high (*e.g.,* on a day with strong wind and high waves), an anthropogenic sound source would not be detectable as far away as would be possible under quieter conditions and would itself be masked. The Puget Sound area contains active commercial shipping, ferry operations, and commercial fishing as well as numerous recreational and other commercial vessels, and background sound levels in the area are already elevated.

Airborne Acoustic Effects—Pinnipeds that occur near the project site could be exposed to airborne sounds associated with pile driving and removal that have the potential to cause behavioral harassment, depending on their distance from pile driving activities. Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA.

Airborne noise would primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels elevated above the acoustic criteria. We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled-out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon the area and move further from the source. However, these animals would likely previously have been 'taken' because of exposure to underwater sound above the behavioral harassment thresholds, which are generally larger than those associated with airborne sound. There are no haulouts near the project sites. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Marine Mammal Habitat Effects

WSDOT's proposed construction activities could have localized, temporary impacts on marine mammal habitat, including prey, by increasing in-water sound pressure levels and slightly decreasing water quality. Increased noise levels may affect acoustic habitat (see masking discussion above) and adversely affect marine mammal prey in the vicinity of the project areas (see discussion below). During impact and vibratory pile driving or removal, elevated levels of underwater noise would ensonify the project areas where both fishes and mammals occur and could affect foraging success. Additionally, marine mammals may avoid the area during construction, however, displacement due to noise is expected to be temporary and is not expected to result in long-term effects to the individuals or populations. Construction activities are of short duration and would likely have temporary impacts on marine mammal habitat through increases in underwater and airborne sound.

A temporary and localized increase in turbidity near the seafloor would occur in the immediate area surrounding the area where piles are installed or removed. In general, turbidity associated with pile installation is localized to about a 25-ft (7.6-m) radius around the pile (Everitt *et al.,* 1980). The sediments of the project site will settle out rapidly when disturbed. Cetaceans are not expected to be close enough to the pile driving areas to experience effects of turbidity, and any pinnipeds could avoid localized areas of turbidity. Local currents are anticipated to disburse any additional suspended sediments produced by project activities at moderate to rapid rates depending on tidal stage. Therefore, we expect the impact from increased turbidity levels to be discountable to marine mammals and do not discuss it further.

In-Water Construction Effects on Potential Foraging Habitat

The area likely impacted by the project is relatively small compared to the available habitat in Puget Sound. The area is highly influenced by anthropogenic activities. The total seafloor area affected by pile installation and removal is a small area compared to the vast foraging area available to marine mammals in the area. At best, the impact area provides marginal foraging habitat for marine mammals and fishes. Furthermore, pile driving and removal at the project site would not obstruct long-term movements or migration of marine mammals.

Avoidance by potential prey (*i.e.,* fish or, in the case of transient killer whales, other marine mammals) of the immediate area due to the temporary loss of this foraging habitat is also possible. The duration of fish and marine mammal avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. Any behavioral avoidance by fish or marine mammals of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity.

In-Water Construction Effects on Potential Prey—Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, zooplankton, other marine mammals). Marine mammal prey varies by species, season, and location. Here, we describe studies regarding the effects of noise on known marine mammal prey other than other marine mammals (which have been discussed earlier).

Fish utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.,* Zelick and Mann, 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.,* 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to noise depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish; several are based on studies in support of large, multiyear bridge construction projects (*e.g.,* Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Several studies have demonstrated that impulse sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017). However, some studies have shown no or slight reaction to impulse sounds (*e.g.,* Pena *et al.,* 2013; Wardle *et al.,* 2001; Jorgenson and Gyselman, 2009; Popper *et al.,* 2015).

SPLs of sufficient strength have been known to cause injury to fish and fish mortality. However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012a) showed that a TTS of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.,* 2012b; Casper *et al.,* 2013).

The most likely impact to fishes from pile driving and removal and construction activities at the project areas would be temporary behavioral avoidance of the area. The duration of fish avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated.

Construction activities, in the form of increased turbidity, have the potential to adversely affect forage fish in the project areas. Forage fish form a significant prey base for many marine mammal species that occur in the project areas. Increased turbidity is expected to occur in the immediate vicinity (on the order of 10 ft (3 m) or less) of construction activities. However, suspended sediments and particulates are expected to dissipate quickly within a single tidal cycle. Given the limited area affected and high tidal dilution rates any effects on forage fish are expected to be minor or negligible. Finally, exposure to turbid waters from construction activities is not expected to be different from the current exposure; fish and marine mammals in Eagle Harbor are routinely exposed to substantial levels of suspended

sediment from natural and anthropogenic sources.

In summary, given the short daily duration of sound associated with individual pile driving events and the relatively small areas being affected, pile driving activities associated with the proposed actions are not likely to have a permanent, adverse effect on any fish habitat, or populations of fish species. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. Thus, we conclude that impacts of the specified activities are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment (in the form of behavioral disturbance and TTS), as use of the acoustic sources (*i.e.,* vibratory or impact pile driving and removal) have the potential to result in disruption of behavioral patterns and cause a temporary loss in hearing sensitivity for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result for porpoises and harbor seals because predicted auditory injury zones are larger. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (rms SPL) of 120 dB (referenced to 1 micropascal (re 1 μPa)) for continuous (*e.g.,* vibratory pile-driving, drilling) and above rms SPL 160 dB re 1 μPa for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources.

WSDOT's proposed activities includes the use of continuous (vibratory hammer) and impulsive (impact hammer) sources, and therefore the 120 and 160 dB re 1 μPa (rms) thresholds are applicable.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). WSDOT's activities include the use of impulsive (impact hammer) and non-impulsive (vibratory hammer) sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 5—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6:* $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$: 201 dB.

TABLE 5—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT—Continued

Hearing group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$*:* 232 dB; $L_{E,OW,24h}$*:* 203 dB	*Cell 10:* $L_{E,OW,24h}$*:* 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 µPa, and cumulative sound exposure level (L_E) has a reference value of 1µPa²s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI, 2013). However, ANSI defines peak sound pressure as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript ''flat'' is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project areas is the existing background noise plus additional construction noise from the proposed project. Marine mammals are expected to be affected by sound generated by the primary components of the project (*i.e.,* impact and vibratory pile driving).

In order to calculate distances to the Level A harassment and Level B harassment thresholds for the methods and piles being used in these projects, NMFS used acoustic monitoring data from previous pile driving at the Bainbridge Island Ferry Terminal (impact installation of 24-in steel piles) and Eagle Harbor Maintenance Facility (impact installation of 30-in steel piles), as well as pile driving at other locations within Puget Sound to develop source levels for the various pile types, sizes, and methods for the two projects (Table 6). A source level for vibratory driving of 18-in steel piles is not available so it is conservatively assumed to be equivalent to the source level for 24-in steel piles.

TABLE 6—EXPECTED PROJECT SOUND SOURCE LEVELS

Pile type and size (in)	Method	Source level (dB re 1 µPa)	Source level measurement distance (m)	Reference
12-in timber	Vibratory removal	152 dB rms	10	Greenbusch Group (2018).
18-in and 24-in steel	Vibratory installation and removal.	166 dB rms	10	WSDOT (2020) [1].
30-in steel	Vibratory installation and removal.	176 dB rms	6	WSDOT (2020) [1].
36-in steel	Vibratory installation	184 dB rms	10	WSDOT (2020) [1].
24-in steel	Impact installation	206 dB peak; 179 dB SEL; 195 dB rms.	10	WSDOT (2020) [1].
30-in steel	Impact installation	194 dB peak; 182 dB SEL; 184 dB rms.	10	WSDOT (2020) [1].
36-in steel	Impact installation	205 dB peak; 178 dB SEL; 191 dB rms.	10	WSDOT (2020) [1].

[1] WSDOT Biological Assessment Manual Table 7–15.

Level B Harassment Zones

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

TL = B * Log10 (R1/R2)

Where:

TL = transmission loss in dB

B = transmission loss coefficient; for practical spreading equals 15

R1 = the distance of the modeled SPL from the driven pile, and

R2 = the distance from the driven pile of the initial measurement

The recommended TL coefficient for most nearshore environments is the practical spreading value of 15. This value results in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions, which is the most appropriate assumption for WSDOT's proposed activities in the absence of specific modelling. The Level B harassment zones for WSDOT's proposed activities are shown in Table 7.

Level A Harassment Zones

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically

going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as pile installation and removal, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur PTS. The isopleths generated by the User Spreadsheet used the same TL coefficient as the Level B harassment zone calculations (*i.e.,* the practical spreading value of 15). Inputs used in the User Spreadsheet (*e.g.,* number of piles per day, duration and/or strikes per pile) are presented in Tables 1 and 2, and the resulting isopleths are reported below in Table 7.

TABLE 7—LEVEL A HARASSMENT AND LEVEL B HARASSMENT ZONES

Pile size/type	Pile driving method	Level A harassment zone (m)					Level B harassment zone (m)
		LF cetaceans	MF cetaceans	HF cetaceans	Phocids	Otariids	
12-in timber	Vibratory removal.	4.1	0.4	6.1	2.5	0.2	[a] 1,360
18-in steel	Vibratory installation/removal.	23.4	2.1	34.5	14.2	1.0	[a] 11,659
24-in steel	Vibratory installation/removal.	27.1	2.4	40.1	16.5	1.2	[a] 11,659
30-in steel	Vibratory installation/removal.	65.1	5.8	96.2	39.5	2.8	[a b] 32,470
36-in steel	Vibratory installation.	485.1	43.0	717.2	294.9	20.7	[a b] 184,785
24-in steel	Impact installation.	784.8	27.9	934.8	420.0	30.6	[c] 2,154
30-in steel	Impact installation.	1,359.6	48.4	1,619.5	727.6	53.0	[c] 2,154398
36-in steel	Impact installation.	795.9	28.3	948.0	425.9	31.0	[c] 2,1541,166

[a] Distance to 120 dB rms threshold.
[b] Distance to Level B harassment threshold without obstruction; however for these projects, 13,345 m is the maximum in-water distance until land is reached.
[c] Distance to 160 dB rms threshold.

Marine Mammal Occurrence and Take Calculation and Estimation

In this section we provide information about the occurrence of marine mammals, including density or other relevant information, that will inform the quantitative estimate of the take that is reasonably likely to occur and proposed for authorization. Unless otherwise specified, the term ''pile driving'' in this section, and all following sections, may refer to either pile installation or removal. WSDOT first estimated take for both projects using the areas ensonified above the Level B harassment threshold and density estimates for marine mammals in Puget Sound. Density estimates for all species except harbor porpoises were from the U.S. Navy's Marine Species Density Database (MSDD) for the Northwest Training and Testing (NWTT) Study Area (U.S. Navy, 2019). For harbor porpoises, WSDOT used the density estimate from Evenson (2016) as it was considered more conservative than the density estimate for harbor porpoises from the NWTT MSDD. However, for all species except harbor seals and harbor porpoises, WSDOT did not consider the resulting take estimates to be realistic (*i.e.,* either over- or underestimated take). Instead, WSDOT compiled monitoring results from pile driving between August 2017 and February 2021 at the Seattle Ferry Terminal Multimodal Project at Colman Dock (WSDOT 2021) (Table 8). Because the Level B harassment zones from vibratory pile driving at Colman Dock extended to or near the Bainbridge Island shoreline, and because the Level B harassment zones from vibratory pile driving at the Bainbridge Ferry Terminal and Eagle Harbor Maintenance Facility extend to the shoreline, WSDOT considered the monitoring results from the Seattle Multimodal Project to be the most relevant and comprehensive sightings data available for the project areas. Based on the Seattle Multimodal Project monitoring results, WSDOT used their best professional judgement to estimate the number of marine mammals that may be taken incidental to the proposed activities.

NMFS has carefully reviewed WSDOT's analysis and concludes that it represents an appropriate and accurate method for estimating incidental take caused by WSDOT's activities.

TABLE 8—MARINE MAMMAL DENSITY AND SIGHTINGS

Species	Density/km^2	Sightings total	Average sightings/day (372 days)	Maximum one-day sightings	Take requested
Harbor Seal	3.91	1,939	5.21	43	Yes.
Northern Elephant Seal	[1] 0.0	1	0.003	1	Yes.
California Sea Lion	0.0152–0.2211	2,625	7.05	38	Yes.
Steller Sea Lion	0.0010–0.0478	100	0.27	10	Yes.
Unidentified pinniped	N/A	118	N/A	9	N/A.
Killer Whale Southern Resident	0.000009–0.007828	297	0.80	26	No.
Killer Whale Transient	0.001582–0.002373	47	0.13	20	Yes.

TABLE 8—MARINE MAMMAL DENSITY AND SIGHTINGS—Continued

Species	Density/km²	Sightings total	Average sightings/day (372 days)	Maximum one-day sightings	Take requested
Gray Whale	0.000086	4	0.011	1	Yes.
Minke Whale	0.00045	1	0.003	1	Yes.
Unidentified large whale	N/A	2	N/A	1	N/A.
Unidentified small whale	N/A	10	N/A	9	N/A.
Harbor Porpoise	0.58	413	1.11	40	Yes.
Dall's Porpoise	0.00045	8	0.02	5	Yes.
Pacific White-sided Dolphin	0.0	2	0.005	2	Yes.
Long-beaked Common Dolphin	0.0	2	0.005	1	Yes.
Common Bottlenose Dolphin	0.0	6	0.02	2	Yes.
Unidentified dolphin/porpoise	N/A	42	N/A	5	N/A.

Gray Whale

WSDOT estimated that up to 20 gray whales could be taken by Level B harassment from each project, for a total of 40 takes of gray whales by Level B harassment. In consideration of the infrequent occurrence of gray whales in the project areas, the proposed mitigation and monitoring measures that WSDOT would be required to comply with, including marine mammal monitoring and coordination with Orca Network that would alert WSDOT to the presence of large whales in the project area (see Proposed Mitigation), and given the size and visibility of gray whales, WSDOT would be able to detect gray whales and stop work before gray whales could enter the Level A harassment zones. Therefore, it is unlikely that any gray whales would be taken by Level A harassment. No take of gray whales by Level A harassment is requested or proposed to be authorized.

Minke Whale

WSDOT estimated that up to 20 minke whales could be taken by Level B harassment from each project, for a total of 40 takes of minke whales by Level B harassment. Like gray whales, in consideration of the infrequent occurrence of minke whales in the project areas, the proposed mitigation and monitoring measures that WSDOT would be required to comply with, including marine mammal monitoring and coordination with Orca Network (see Proposed Mitigation), and given the size and visibility of minke whales, WSDOT would be able to detect minke whales and stop work before minke whales could enter the Level A harassment zones. Therefore, it is unlikely that any minke whales would be taken by Level A harassment. No take of minke whales by Level A harassment is requested or proposed to be authorized.

Long-Beaked Common Dolphin

WSDOT estimated that up to 20 long-beaked common dolphins could be taken by Level B harassment from each project, for a total of 40 takes of long-beaked common dolphins by Level B harassment. The Level A harassment zones for mid-frequency cetaceans are all less than 50 m. Given the visibility of long-beaked common dolphins, WSDOT would be able to cease pile driving before long-beaked common dolphins could enter the Level A harassment zone. No take of long-beaked common dolphins by Level A harassment is requested or proposed to be authorized.

Bottlenose Dolphin

WSDOT estimated that up to 20 bottlenose dolphins could be taken by Level B harassment from each project, for a total of 40 takes of bottlenose dolphins by Level B harassment. The Level A harassment zones for mid-frequency cetaceans are all less than 50 m. Given the visibility of bottlenose dolphins, WSDOT would be able to cease pile driving before bottlenose dolphins could enter the Level A harassment zone. No take of bottlenose dolphins by Level A harassment is requested or proposed to be authorized.

Pacific White-Sided Dolphin

WSDOT estimated that up to 20 Pacific white-sided dolphins could be taken by Level B harassment from each project, for a total of 40 takes of Pacific white-sided dolphins by Level B harassment. The Level A harassment zones for mid-frequency cetaceans are all less than 50 m. Given the visibility of long-beaked common dolphins, WSDOT would be able to cease pile driving before long-beaked common dolphins could enter the Level A harassment zone. No take of long-beaked common dolphins by Level A harassment is requested or proposed to be authorized.

Killer Whale (Transient)

WSDOT estimated that up to 60 transient killer whales could be taken by Level B harassment from each project, for a total of 120 takes of killer whales by Level B harassment. The Level A harassment zones for mid-frequency cetaceans are all less than 50 m. Given the visibility of killer whales, WSDOT would be able to cease pile driving before killer whales could enter the Level A harassment zone. No take of killer whales by Level A harassment is requested or proposed to be authorized.

As stated above, no take of Southern Resident killer whales is expected or proposed to be authorized.

Harbor Porpoise

To estimate the number of harbor porpoises that may be taken by Level B harassment from the two projects, WSDOT calculated the area ensonified above the Level B harassment threshold for each pile size, type, and method for both projects. WSDOT then multiplied the estimated density of harbor porpoises in the area (0.58 per km²; Evenson 2016) by the ensonified area and the expected days of work for each project element (Table 9).

TABLE 9—ESTIMATED TAKE OF HARBOR PORPOISES BY LEVEL B HARASSMENT

Pile size, type, and method	Bainbridge ensonified area (km^2)	Bainbridge days of work	Eagle Harbor ensonified area (km^2)	Eagle Harbor days of work	Bainbridge takes by Level B harassment by pile size, type, and method	Eagle Harbor takes by Level B harassment by pile size, type, and method
12-in timber vibratory	0.5	5	0.8	13	3	6
18-in steel vibratory	N/A	0	23.2	3	0	27
24-in steel vibratory	2.3	2	23.2	3	3	40
30-in steel vibratory	2.3	23	23.2	4	320	53
36-in steel vibratory	2.3	6	23.2	4	84	53
24-in steel impact	0.9	13	0.87	3	17	2
30-in steel impact	0.4	2	N/A	0	3	0
36-in steel impact	0.9	6	0.87	1	8	1
Total					298	183

The areas ensonified above the Level A harassment threshold for high-frequency cetaceans has been omitted from the areas ensonified above the Level B harassment threshold presented in Table 9. For impact installation of 30-in steel piles, the Level A harassment zone for high-frequency cetaceans is approximately 1,620 m. To estimate the number of harbor porpoises that may be present within the Level A harassment zone, WSDOT used the average sightings rate from the Seattle Multimodal Project at Colman Dock (0.691 harbor porpoises per day; Table 8) multiplied by the days of impact pile driving expected for each project (27 days for the Bainbridge Project and 8 days for the Eagle Harbor Project) to estimate that 19 and 6 harbor porpoises may be taken by Level A harassment from the Bainbridge Project and Eagle Harbor Project, respectively, for a total of 25 takes of harbor seals by Level A harassment.

Dall's Porpoise

WSDOT estimated that up to 20 Dall's porpoises could be taken by Level B harassment from each project, for a total of 40 takes of Dall's porpoises by Level B harassment.

For impact installation of 30-in steel piles, the Level A harassment zone for high-frequency cetaceans is approximately 1,620 m. Dall's porpoises are considered rare in the project area and are unlikely to be present within the Level A harassment zones but WSDOT conservatively estimates that no more than 5 Dall's porpoises could enter the Level A harassment zones of each project, for a total of 10 takes of Dall's porpoises by Level A harassment.

California Sea Lion

Over the course of 372 days of monitoring for the Seattle Multimodal Project at Colman Dock, the average number of California sea lions observed per day was 7.05 (Table 8). WSDOT used that average sightings rate multiplied by the days of work for each project (57 days for the Bainbridge Project and 31 days for the Eagle Harbor Project) to estimate that 402 and 219 California sea lions may be taken by Level B harassment from the Bainbridge Project and Eagle Harbor Project, respectively, for a total of 621 takes of California sea lions by Level B harassment.

The largest Level A harassment zone for otariid pinnipeds is 53 m. WSDOT would be required to implement a 60 m shutdown zone for otariids for all pile driving activities. At that close range, WSDOT would be able to detect California sea lions and implement the required shutdown measures before California sea lions could enter the Level A harassment zone. Therefore, no takes of California sea lions by Level A harassment are requested or proposed to be authorized.

Steller Sea Lion

WSDOT estimated that 180 Steller sea lions could be taken by Level B harassment from each project, for a total of 360 takes of Steller sea lions by Level B harassment. The largest Level A harassment zone for otariid pinnipeds is 53 m. WSDOT would be required to implement a 60 m shutdown zone for otariids for all pile driving activities. At that close range, WSDOT would be able to detect Steller sea lions and implement the required shutdown measures before Steller sea lions could enter the Level A harassment zone. Therefore, no takes of Steller sea lions by Level A harassment are requested or proposed to be authorized.

Harbor Seal

To estimate the number of harbor seals that may be taken by Level B harassment from the two projects, WSDOT calculated the area ensonified above the Level B harassment threshold for each pile size, type, and method for both projects. WSDOT then multiplied the estimated density of harbor seals in the area (3.91 per km^2; Navy 2019) by the ensonified area and the expected days of work for each project element (Table 10). In total, WSDOT estimates that 3,450 harbor seals may be taken by Level B harassment.

TABLE 10—ESTIMATED TAKE OF HARBOR SEALS BY LEVEL B HARASSMENT

Pile size, type, and method	Bainbridge ensonified area (km^2)	Bainbridge days of work	Eagle Harbor ensonified area (km^2)	Eagle Harbor days of work	Bainbridge takes by pile size, type, and method	Eagle Harbor takes by pile size, type, and method
12-in timber vibratory	1.5	5	1.6	13	30	81
18-in steel vibratory	N/A	0	24.1	3	0	188
24-in steel vibratory	24.0	2	24.1	3	188	283
30-in steel vibratory	24.0	23	24.1	4	2,158	377
36-in steel vibratory	24.0	6	24.1	4	563	377
24-in steel impact	2.0	13	1.66	3	102	20

TABLE 10—ESTIMATED TAKE OF HARBOR SEALS BY LEVEL B HARASSMENT—Continued

Pile size, type, and method	Bainbridge ensonified area (km^2)	Bainbridge days of work	Eagle Harbor ensonified area (km^2)	Eagle Harbor days of work	Bainbridge takes by pile size, type, and method	Eagle Harbor takes by pile size, type, and method
30-in steel impact	1.3	2	N/A	0	10	0
36-in steel impact	2.0	6	1.66	1	47	7
Total					2,117	1,333

The areas ensonified above the Level A harassment threshold for high-frequency cetaceans has been omitted from the areas ensonified above the Level B harassment threshold presented in Table 10. For impact installation of 30-in steel piles, the Level A harassment zone for phocid pinnipeds is approximately 728 m. To estimate the number of harbor seals that may be present within the Level A harassment zone, WSDOT used the average sightings rate from the Seattle Multimodal Project at Colman Dock (5.21 harbor seals per day; Table 8) multiplied by the days of impact pile driving expected for each project (27 days for the Bainbridge Project and 8 days for the Eagle Harbor Project) to estimate that 141 and 42 harbor seals may be taken by Level A harassment from the Bainbridge Project and Eagle Harbor Project, respectively, for a total of 183 takes of harbor seals by Level A harassment.

Northern Elephant Seal

Individual elephant seals have occasionally been reported in central Puget Sound (*e.g.,* Orca Network, 2020) but are considered rare in the project areas. WSDOT estimated that up to 10 northern elephant seals could be taken by Level B harassment from each project, for a total of 20 takes of northern elephant seals by Level B harassment. The largest Level A harassment zone (728 m) occurs during impact installation of 30-in steel pipe piles (Table 7). It is unlikely that northern elephant seals would be found within this zone, and even more unlikely that northern elephant seals would be found within the Level A harassment zones for vibratory pile driving (up to 295 m). However, even if northern elephant seals were encountered in the project areas, at that close range, WSDOT would be able to detect them and implement the required shutdown measures before any northern elephant seals could enter the Level A harassment zones. Therefore, no take of northern elephant seals by Level A harassment is requested or proposed to be authorized.

TABLE 11—PROPOSED TAKE OF MARINE MAMMALS BY LEVEL A AND LEVEL B HARASSMENT FROM THE BAINBRIDGE PROJECT BY SPECIES AND STOCK

Species	Stock	Proposed take by Level B harassment	Proposed take by Level A harassment
Gray whale	Eastern North Pacific	20	0
Minke whale	California/Oregon/Washington	20	0
Killer whale	West Coast Transient	60	0
Bottlenose dolphin	California Coastal	20	0
Long-beaked common dolphin	California	20	0
Pacific white-sided dolphin		20	0
Harbor porpoise	Washington Inland Waters	298	19
Dall's porpoise	California/Oregon/Washington	20	5
California sea lion	U.S	402	0
Steller sea lion	Eastern	180	0
Northern elephant seal	California Breeding	10	0
Harbor seal	Washington Northern Inland Waters	2,117	141

TABLE 12—PROPOSED TAKE OF MARINE MAMMALS BY LEVEL A AND LEVEL B HARASSMENT FROM THE EAGLE HARBOR PROJECT BY SPECIES AND STOCK

Species	Stock	Proposed take by Level B harassment	Proposed take by Level A harassment
Gray whale	Eastern North Pacific	20	0
Minke whale	California/Oregon/Washington	20	0
Killer whale	West Coast Transient	60	0
Bottlenose dolphin	California Coastal	20	0
Long-beaked common dolphin	California	20	0
Pacific white-sided dolphin		20	0
Harbor porpoise	Washington Inland Waters	183	6
Dall's porpoise	California/Oregon/Washington	20	5
California sea lion	U.S	219	0
Steller sea lion	Eastern	180	0
Northern elephant seal	California Breeding	10	0
Harbor seal	Washington Northern Inland Waters	1,333	42

TABLE 13—TOTAL PROPOSED TAKE OF MARINE MAMMALS BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND STOCK AND PERCENT OF TAKE BY STOCK

Species	Stock	Total proposed take by Level A harassment	Total proposed take by Level B harassment	Total proposed take	Percent of stock
Gray whale	Eastern North Pacific	0	40	40	0.2
Minke whale	California/Oregon/Washington	0	40	40	11.0
Killer whale	West Coast Transient	0	120	120	34.4
Bottlenose dolphin	California Coastal	0	40	40	8.8
Long-beaked common dolphin	California	0	40	40	3.2
Pacific white-sided dolphin	California/Oregon/Washington	0	40	40	0.2
Harbor porpoise	Washington Inland Waters	25	481	506	5.0
Dall's porpoise	California/Oregon/Washington	10	40	50	0.3
California sea lion	U.S	0	621	621	0.24
Steller sea lion	Eastern	0	360	360	0.83
Northern elephant seal	California Breeding	0	20	20	0.01
Harbor seal	Washington Northern Inland Waters	183	3,450	3,633	32.9

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost and impact on operations.

Shutdown Zones

Before the commencement of in-water construction activities, WSDOT would establish shutdown zones for all activities. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Pile driving would also not commence until all marine mammals are clear of their respective shutdown zones. Shutdown zones are established in consideration of the Level A harassment zones and therefore typically vary based on the activity type and marine mammal hearing group. However, rather than establishing different shutdown zones for each hearing group for each project element, WSDOT proposed to simplify the shutdown zones and implement only 1 or 2 shutdown zones for each hearing group across all project elements (Table 14). For example, the 720 m shutdown zone proposed to be implemented for low-frequency and high-frequency cetaceans for all vibratory pile driving activities encompasses both the largest Level A harassment zone for high-frequency cetaceans (717.2 m; see Table 7) and the largest Level A harassment zone for low-frequency cetaceans (485.1 m; see Table 7). This conservatively protects animals in both hearing groups, simplifies analysis and monitoring, and presents minimal risks to implementing the project, as marine mammals in these hearing groups are unlikely to be present within 720 m of the construction site during pile driving activities. For impact pile driving, WSDOT proposes to retain the 720 m shutdown zone for high-frequency cetaceans but increase the shutdown zone for low-frequency cetaceans to 2,175 m which encompasses the largest Level B harassment zone for impact pile driving, and is also the proposed shutdown zone for preventing take of unauthorized species (*e.g.,* Southern Resident killer whales, humpback whales) (Table 14). The Level A harassment zones for high-frequency cetaceans from impact pile driving are all greater than 720 m (Table 7), thus any high-frequency cetacean that enters the Level A harassment zone beyond 720 m would be recorded as taken by Level A harassment.

At minimum, the shutdown zone for all hearing groups and all activities would be 10 m. For in-water heavy machinery work other than pile driving (*e.g.,* standard barges, *etc.*), if a marine mammal comes within 10 m, operations would cease and vessels would reduce speed to the minimum level required to maintain steerage and safe working conditions. This type of work could include, for example, the movement of the barge to the pile location or positioning of the pile on the substrate via a crane.

WSDOT would also establish shutdown zones for all marine mammals for which take has not been authorized or for which incidental take has been authorized but the authorized number of takes has been met. These zones are equivalent to the Level B harassment zones for each activity (see Table 14).

WSDOT would also implement shutdown measures for Southern Resident killer whales and humpback whales. If Southern Resident killer whales or humpback whales are sighted within the vicinity of the project areas and are approaching the Level B harassment zone (see Table 14), WSDOT would shut down the pile driving equipment to avoid possible take of these species. If a killer whale

approaches the Level B harassment zone during pile driving, and it is unknown whether it is a Southern Resident killer whale or a transient killer whale, it would be assumed to be a Southern Resident killer whale and WSDOT would implement the shutdown measure.

If a Southern Resident killer whale, unidentified killer whale, or humpback whale enters the Level B harassment zone undetected, in-water pile driving would be suspended until the whale exits the Level B harassment zone, or 15 minutes have elapsed with no sighting of the animal, to avoid further Level B harassment.

TABLE 14—SHUTDOWN ZONES FOR PIER 58 RECONSTRUCTION

Pile type and method	Shutdown zone (m)					
	LF cetacean	MF cetacean	HF cetacean	Phocids	Otariids	Southern resident killer whales, humpback whales, and other unauthorized species
12-in timber vibratory	720	60	720	60	60	2,175
18-in steel vibratory	720	60	720	60	60	[a] 13,345
24-in steel vibratory	720	60	720	60	60	[a] 13,345
30-in steel vibratory	720	60	720	60	60	[a] 13,345
36-in steel vibratory	720	60	720	60	60	[a] 13,345
24-in steel impact	2,175	60	720	60	60	2,175
30-in steel impact	2,175	60	720	60	60	2,175
36-in steel impact	2,175	60	720	60	60	2,175

[a] 13,345 m is the maximum distance sound can travel before reaching land.

Protected Species Observers

The placement of protected species observers (PSOs) during all pile driving activities (described in the Proposed Monitoring and Reporting section) would ensure that the entire shutdown zone is visible. Should environmental conditions deteriorate such that the entire shutdown zone would not be visible (*e.g.,* fog, heavy rain), pile driving would be delayed until the PSO is confident marine mammals within the shutdown zone could be detected.

Monitoring for Level A and Level B Harassment

PSOs would monitor the Level B harassment zones to the extent practicable, and all of the Level A harassment zones. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring zones enable observers to be aware of and communicate the presence of marine mammals in the project areas outside the shutdown zones and thus prepare for a potential cessation of activity should the animal enter the shutdown zone.

Pre-Activity Monitoring

Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs would observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone would be considered cleared when a marine mammal has not been observed within the zone for that 30-minute period. If a marine mammal is observed within the shutdown zones listed in Table 14, pile driving activity would be delayed or halted. If pile driving is delayed or halted due to the presence of a marine mammal, the activity would not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zones or 15 minutes have passed without re-detection of the animal. When a marine mammal for which Level B harassment take is authorized is present in the Level B harassment zone, activities would begin and Level B harassment take would be recorded. If work ceases for more than 30 minutes, the pre-activity monitoring of the shutdown zones would commence. A determination that the shutdown zone is clear must be made during a period of good visibility (*i.e.,* the entire shutdown zone and surrounding waters must be visible to the naked eye).

Coordination With Local Marine Mammal Research Network

Prior to the start of pile driving for the day, the PSOs would contact the Orca Network to find out the location of the nearest marine mammal sightings. The Local Marine Mammal Research Network consists of a list of over 600 (and growing) residents, scientists, and government agency personnel in the United States and Canada. Sightings are called or emailed into the Orca Network and immediately distributed to other sighting networks including: the NMFS Northwest Fisheries Science Center, the Center for Whale Research, Cascadia Research, the Whale Museum Hotline, and the British Columbia Sightings Network.

Sightings information collected by the Orca Network includes detection by hydrophone. The SeaSound Remote Sensing Network is a system of interconnected hydrophones installed in the marine environment of Haro Strait (west side of San Juan Island) to study orca communication, in-water noise, bottom fish ecology, and local climatic conditions. A hydrophone at the Port Townsend Marine Science Center measures average in-water sound levels and automatically detects unusual sounds. These passive acoustic devices allow researchers to hear when different marine mammals come into the region. This acoustic network, combined with the volunteer visual sighting network allows researchers to document presence and location of various marine mammal species.

Soft Start

Soft-start procedures are used to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors would be required to provide an initial set of three strikes from the hammer at reduced energy, followed by a 30-second waiting period, then two subsequent reduced-

energy strike sets. Soft start would be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

Bubble Curtain

A bubble curtain would be employed during impact installation or proofing of steel piles, unless the piles are driven in the dry, or water is less than 3 ft (0.9 m) in depth. A noise attenuation device would not be required during vibratory pile driving. If a bubble curtain or similar measure is used, it would distribute air bubbles around 100 percent of the piling perimeter for the full depth of the water column. Any other attenuation measure would be required to provide 100 percent coverage in the water column for the full depth of the pile. The lowest bubble ring would be in contact with the mudline for the full circumference of the ring. The weights attached to the bottom ring would ensure 100 percent mudline contact. No parts of the ring or other objects would prevent full mudline contact.

Based on our evaluation of the WSDOT's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Visual Monitoring

Marine mammal monitoring during pile driving activities would be conducted by PSOs meeting NMFS' standards and in a manner consistent with the following:

- Independent PSOs (*i.e.,* not construction personnel) who have no other assigned tasks during monitoring periods would be used;
- At least one PSO would have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization;
- Other PSOs may substitute education (degree in biological science or related field) or training for experience; and
- Where a team of three or more PSOs is required, a lead observer or monitoring coordinator would be designated. The lead observer would be required to have prior experience working as a marine mammal observer during construction.

PSOs would have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

During impact driving of all steel piles, and during vibratory removal of timber piles, WSDOT would have three PSOs stationed to monitor the project area: one at the construction site, one across Eagle Harbor looking toward the construction site, and one on board the Seattle-Bainbridge ferry. For vibratory driving of all steel piles, WSDOT would have five PSOs to monitor the project area: three at the locations described for impact pile driving, with one additional PSO stationed on the Seattle waterfront and one stationed on Alki Beach looking west toward Bainbridge Island.

Monitoring would be conducted 30 minutes before, during, and 30 minutes after all in water construction activities. In addition, observers would record all incidents of marine mammal occurrence, regardless of distance from activity, and would document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

Reporting

A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of pile driving activities, or 60 days prior to a requested date of issuance of any future IHAs for the project, or other projects at the same location, whichever comes first. The marine mammal report would include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report would include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including: (a) How many and what type of piles were driven or removed and the

method (*i.e.,* impact or vibratory); and (b) the total duration of time for each pile (vibratory driving) number of strikes for each pile (impact driving);

- PSO locations during marine mammal monitoring; and
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance.

For each observation of a marine mammal, the following would be reported:

- Name of PSO who sighted the animal(s) and PSO location and activity at time of sighting;
- Time of sighting;
- Identification of the animal(s) (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species;
- Distance and location of each observed marine mammal relative to the pile being driven or hole being drilled for each sighting;
- Estimated number of animals (min/max/best estimate);
- Estimated number of animals by cohort (adults, juveniles, neonates, group composition, etc.);
- Description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.,* no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);
- Number of marine mammals detected within the harassment zones, by species; and
- Detailed information about implementation of any mitigation (*e.g.,* shutdowns and delays), a description of specified actions that ensued, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days, the draft reports would constitute the final reports. If comments are received, a final report addressing NMFS' comments would be required to be submitted within 30 days after receipt of comments. All PSO datasheets and/or raw sighting data would be submitted with the draft marine mammal report.

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, WSDOT would report the incident to the Office of Protected Resources (OPR) (*PR.ITP.MonitoringReports@noaa.gov*), NMFS and to the West Coast Region (WCR) regional stranding coordinator as soon as feasible. If the death or injury was clearly caused by the specified activity, WSDOT would immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHAs. WSDOT would not resume their activities until notified by NMFS.

The report would include the following information:

1. Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
2. Species identification (if known) or description of the animal(s) involved;
3. Condition of the animal(s) (including carcass condition if the animal is dead);
4. Observed behaviors of the animal(s), if alive;
5. If available, photographs or video footage of the animal(s); and
6. General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

Pile driving activities from the Bainbridge and Eagle Harbor Projects have the potential to disturb or displace marine mammals. Specifically, the project activities may result in take, in the form of Level A and Level B harassment, from underwater sounds generated from pile driving. Potential takes could occur if individuals are present in the ensonified zone when these activities are underway.

The takes from Level A and Level B harassment would be due to potential behavioral disturbance, TTS, and PTS. No serious injury or mortality is anticipated given the nature of the activities and measures designed to minimize the possibility of injury to marine mammals. The potential for harassment is minimized through the construction method and the implementation of the planned mitigation measures (see Proposed Mitigation section).

To avoid repetition, the majority of our analysis applies to all the species listed in Table 3, given that the anticipated effects of these projects on different marine mammal stocks are expected to be relatively similar in nature. Where there are special circumstances for a species or stock (*e.g.,* gray whales), they are included as a separate subsection below.

NMFS has identified key factors which may be employed to assess the level of analysis necessary to conclude whether potential impacts associated with a specified activity should be considered negligible. These include (but are not limited to) the type and magnitude of taking, the amount and importance of the available habitat for the species or stock that is affected, the duration of the anticipated effect to the species or stock, and the status of the species or stock. The following factors support negligible impact determinations for all affected stocks.

Take by Level A harassment is proposed for three species (harbor seals, harbor porpoise, and Dall's porpoise) to account for the possibility that an animal could enter a Level A harassment zone prior to detection, and remain within that zone for a duration long enough to incur PTS. Any take by Level A harassment is expected to arise from, at most, a small degree of PTS, *i.e.,* minor degradation of hearing capabilities within regions of hearing that align most completely with the

energy produced by impact pile driving (*i.e.,* the low-frequency region below 2 kilohertz (kHz)), not severe hearing impairment or impairment within the ranges of greatest hearing sensitivity. Animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of PTS. Two of the 3 species for which Level A harassment is proposed to be authorized are high-frequency cetaceans (harbor porpoise and Dall's porpoise), and the hearing ability of the third species for which Level A harassment is proposed to be authorized (harbor seal) below 2 kHz is also poor (NMFS, 2018). Given the hearing ranges of these three species, PTS incurred at the low frequencies of pile driving noise would not interfere either with conspecific communication or echolocation, and therefore would not be expected to impact on the survival or reproductive abilities of the affected individuals, let alone the stock or population.

As described above, NMFS expects that marine mammals would likely move away from an aversive stimulus, especially at levels that would be expected to result in PTS, given sufficient notice through use of soft start. WSDOT would also be required to shut down pile driving activities if marine mammals approach within hearing group-specific zones (see Table 14), further minimizing the likelihood and degree of PTS that would be incurred. Even absent mitigation, no serious injury or mortality from construction activities is anticipated or proposed to be authorized.

Effects on individuals that are taken by Level B harassment in the form of behavioral disruption, on the basis of reports in the literature as well as monitoring from other similar activities, will likely be limited to reactions such as avoidance, increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.,* Thorson and Reyff 2006). Most likely, individuals would simply move away from the sound source and temporarily avoid the area where pile driving is occurring. If sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activities are occurring, particularly as the project is located in a busy harbor with high amounts of vessel traffic, including large ferry boats. We expect that any avoidance of the project areas by marine mammals would be temporary in nature and that any marine mammals that avoid the project areas during construction would not be permanently displaced. Short-term avoidance of the project areas and energetic impacts of interrupted foraging or other important behaviors is unlikely to affect the reproduction or survival of individual marine mammals, and the effects of behavioral disturbance on individuals is not likely to accrue in a manner that would affect the rates of recruitment or survival of any affected stock.

Additionally, and as noted previously, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. However, since the hearing sensitivity of individuals that incur TTS is expected to recover completely within minutes to hours, it is unlikely that the brief hearing impairment would affect the individual's long-term ability to forage and communicate with conspecifics, and would therefore not likely impact reproduction or survival of any individual marine mammal, let alone adversely affect rates of recruitment or survival of the species or stock.

The projects are also not expected to have significant adverse effects on affected marine mammals' habitats. The project activities will not modify existing marine mammal habitat for a significant amount of time. The activities may cause some fish to leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities and the relatively small area of the habitat that may be affected (with no known particular importance to marine mammals), the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences. Aside from the biologically important area (BIA) for gray whales described below, there are no known areas of importance for other marine mammals, such as feeding or pupping areas, in the project area.

For all species and stocks, take would occur within a limited, relatively confined area (Eagle Harbor within central Puget Sound) of the stocks' ranges. Given the availability of suitable habitat nearby, any displacement of marine mammals from the project areas is not expected to affect marine mammals' fitness, survival, and reproduction due to the limited geographic area that will be affected in comparison to the much larger habitat for marine mammals in Puget Sound. Level A harassment and Level B harassment will be reduced to the level of least practicable adverse impact to the marine mammal species or stocks and their habitat through use of mitigation measures described herein. Some individual marine mammals in the project areas may be present and be subject to repeated exposure to sound from pile driving on multiple days. However, these individuals would likely return to normal behavior during gaps in pile driving activity. Eagle Harbor is a busy harbor and monitoring reports from previous in-water pile driving activities along the nearby Seattle waterfront (*e.g.,* WSDOT, 2022) indicate that marine mammals continue to remain in the greater project area throughout pile driving activities. Therefore, any behavioral effects of repeated or long duration exposures are not expected to negatively affect survival or reproductive success of any individuals. Thus, even repeated Level B harassment of some small subset of an overall stock is unlikely to result in any effects on rates of reproduction and survival of the stock.

Gray Whales

Puget Sound is part of a BIA for migrating gray whales (Calambokidis *et al.,* 2015). While Eagle Harbor is included in the BIA, gray whales typically remain further north in Puget Sound, primarily in the waters around Whidbey Island (Calambokidis *et al.,* 2018). Gray whales are rarely observed in central Puget Sound, and have never been documented inside Eagle Harbor. Therefore, even though the project areas overlap with the BIA, the infrequent occurrence of gray whales suggests that the projects would have minimal, if any, impact on the migration of gray whales in the BIA, and would therefore not affect reproduction or survival.

There is an ongoing UME for gray whales (see the Description of Marine Mammals in the Area of Specified Activities section of this notice). However, we do not expect the takes estimated to occur and proposed for authorization to exacerbate or compound upon this ongoing UME. As noted previously, no Level A harassment, serious injury, or mortality of gray whales is expected or authorized, and any Level B harassment takes of gray whales would most likely be in the form of behavioral disturbance. Preliminary findings from necropsied gray whales that are considered part of the ongoing UME have shown evidence of emaciation, suggesting that impacts to feeding would be of most concern. However, the project areas have not been identified as important for feeding of gray whales. Additionally, the project areas are not considered important for breeding gray whales. Therefore the projects are unlikely to disrupt any

critical behaviors (*e.g.,* feeding, mating) or have any effect on the reproduction or survival of gray whales, even in light of the ongoing UME.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from these activities are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No mortality or serious injury is anticipated or proposed to be authorized for either project;
- Level A harassment is not anticipated or proposed to be authorized for 9 of the 12 species. For the other three species, Level A harassment would be in the form of a slight degree of PTS;
- Level B harassment would be in the form of behavioral disturbance, primarily resulting in avoidance of the project areas around where impact or vibratory pile driving is occurring, and some low-level TTS that may limit the detection of acoustic cues for relatively brief amounts of time in relatively confined footprint of the activities;
- Nearby areas of similar habitat value within Puget Sound are available for marine mammals that may temporarily vacate the project areas during construction activities for both projects;
- Effects on species that serve as prey for marine mammals from the activities are expected to be short-term and, therefore, any associated impacts on marine mammal feeding are not expected to result in significant or long-term consequences for individuals, or to accrue to adverse impacts on their populations from either project;
- The number of anticipated takes by Level B harassment is relatively low for all stocks for both projects;
- The ensonifed areas from both projects are very small relative to the overall habitat ranges of all species and stocks, and will not adversely affect ESA-designated critical habitat, or cause more than minor impacts in any BIAS or any other areas of known biological importance;
- The lack of anticipated significant or long-term negative effects to marine mammal habitat from either project;
- The efficacy of the mitigation measures in reducing the effects of the specified activities on all species and stocks for both projects; and
- Monitoring reports from similar work in Puget Sound that have documented little to no effect on individuals of the same species that could be impacted by the specified activities from both projects.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

For all species and stocks other than killer whales from the West Coast Transient stock, the proposed take is below one-third of the stock abundance. The proposed take of transient killer whales, as a proportion of the stock abundance is 34.4 percent, if all takes are assumed to occur for unique individuals. In reality, it is unlikely that all takes would occur to different individuals. The project area represents a small portion of the stock's overall range (from Alaska to California (Muto *et al.,* 2019)) and based on sightings reports from the Orca Network, it is reasonable to expect that the same individual transient killer whales would be present within the project area on multiple days during the proposed activities. Therefore, it is more likely that there will be multiple takes of a smaller number of individuals within the project area, such that the number of individuals taken would be less than one third of the population.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to WSDOT for conducting the Bainbridge Island Ferry Terminal Overhead Loading Replacement Project and Eagle Harbor Maintenance Facility Slip F Improvement Project in Bainbridge Island, Washington during the August 2022 to February 2023 in-water work season, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed Bainbridge Island Ferry Terminal Overhead Loading Replacement Project and Eagle Harbor Maintenance Facility Slip F Improvement Project. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform

decisions on the request for this IHA or a subsequent renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, one-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activities section of this notice is planned or (2) the activities as described in the Description of Proposed Activities section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA).
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: August 4, 2022.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–17141 Filed 8–9–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC222]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Coastal Pelagic Species Advisory Subpanel will hold one public meeting.

DATES: The meeting will be held Thursday, September 1, 2022, from 12 p.m. to 2 p.m. Pacific Daylight Time or until business for the day has been completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Jessi Doerpinghaus, Staff Officer, Pacific Council; telephone: (503) 820–2415.

SUPPLEMENTARY INFORMATION: The primary purpose of this online meeting is to discuss and potentially develop work products and recommendations for the Pacific Council's September 2022 meeting. Topics will include changes to Council Operating Procedure 23, ecosystem initiatives, and Council processes and efficiencies. Other items on the Pacific Council's September agenda may be discussed as well. The meeting agenda will be available on the Pacific Council's website in advance of the meeting.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 4, 2022.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–17090 Filed 8–9–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Pribilof Islands, Taking for Subsistence Purposes

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before October 11, 2022.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0699 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Michael T. Williams, Pribilof Islands Program Manager, 222 W 7th Ave., Anchorage,

AK 99513, (907) 271–5117, *Michael.Williams@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for revision and extension of a currently approved collection. The subsistence use of northern fur seals is cooperatively managed by the National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS) and the Tribal Governments of St. Paul and St. George Islands under § 119 of the Marine Mammal Protection Act, 16 U.S.C. 1388 (MMPA) and governed by regulations found in 50 CFR part 216 subpart F, Taking for Subsistence Purposes under the Fur Seal Act (16 U.S.C. 1155). The regulations, laws, and cooperative agreements are focused on conserving northern fur seals through cooperative effort and consultation regarding effective management of human activities related to the subsistence harvests of northern fur seals and Steller sea lions. In 2014, NMFS obtained a collection of information control number (79 FR 65327; November 4, 2014), reviewed the control number in 2017 (82 FR 51218; November 3, 2017), updated the control number in 2019 (84 FR 52372; October 2, 2019, and corrected in 2020 (85 FR 15948; March 20, 2020).

This an information collection for the annual subsistence use male northern fur seals by Alaska Natives (Pribilovians) residing in the communities of St. Paul and St. George, Alaska (Pribilof Islands) under 50 CFR 216 part 216 subpart F. NMFS established regulations regarding the maximum levels for the annual subsistence needs of the Pribilovians after direct consultation with the Tribal Governments of St. Paul and St. George Islands in Alaska and their respective local Native corporations (Tanadgusix and Tanaq). NMFS regulation creates independent northern fur seal subsistence seasons on St. Paul and St. George islands to include male fur seals less than 7 years old, limits on accidental mortality of female northern fur seals, monitoring and reporting through co-management processes established under their respective cooperative agreements. The regulations at 50 CFR 216.72 state that Pribilovians are responsible for reporting their subsistence needs and actual level of subsistence take. NMFS receives electronic copies of the northern fur seal subsistence use reports from the tribal governments of St. Paul and St. George annually. NMFS subsequently posts these reports online (*https://www.fisheries.noaa.gov/alaska/marine-mammal-protection/northern-fur-seal-subsistence-harvest-estimates-and-reports*) and includes the relevant data in the annual Alaska Marine Mammal Stock Assessment Report.

The only change requested to the collection of information at this time is the changing of the collection title from ''Annual Northern Seal Subsistence Harvest Reporting'' to ''Pribilof Islands, Taking for Subsistence Purposes.''

II. Method of Collection

NMFS receives electronic copies of the northern fur seal subsistence use reports from the tribal governments of St. Paul and St. George annually via email.

III. Data

OMB Control Number: 0648–0699.

Form Number(s): None.

Type of Review: Regular submission (revision of a current information collection).

Affected Public: Individuals or households, and State, Local or Tribal Government.

Estimated Number of Respondents: 2.

Estimated Time per Response: Subsistence use report submitted via email estimated to take 40 hours per response for each respondent. The St. George Island Traditional Council submits two reports annually and the Aleut Community of St. Paul Island submits three reports annually.

Estimated Total Annual Burden Hours: 200 hours.

Estimated Total Annual Cost to Public: $80.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: Fur Seal Act (16 U.S.C. 1155).

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–17201 Filed 8–9–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC256]

Marine Mammals; File No. 26678

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that the Matson Laboratory (Carolyn Nistler, Responsible Party), 135 Wooden Shoe Lane, Manhattan, MT 59741, has applied in due form for a permit to import, export, and receive marine mammal parts for scientific research.

DATES: Written, telefaxed, or email comments must be received on or before September 9, 2022.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 26678 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 26678 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth

the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Shasta McClenahan, Ph.D., (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The applicant proposes to receive, import, and export teeth from marine mammal species to perform age analysis including 500 harbor seals (*Phoca vitulina*), 1,000 each of bearded (*Erignathus barbatus*) and spotted seals (*P. largha*), 2,000 ringed seals (*P. hispida*), 500 unidentified pinnipeds (species other than those already mentioned, excluding walrus), and 300 unidentified cetaceans. Sources of foreign and domestic teeth may include subsistence harvests, other authorized researchers or curated collections, law enforcement, and foreign stranded animals. No live animal takes are requested. The requested duration of the permit is five years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: August 5, 2022.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–17144 Filed 8–9–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC254]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Groundfish Advisory Subpanel (GAP) will hold an online meeting, which is open to the public.

DATES: The meeting will be held Thursday, August 25, 2022, from 9 a.m. to 4 p.m., Pacific Time, or until business for each day is completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Brett Wiedoff, Staff Officer, Pacific Council; telephone: (503) 820–2424.

SUPPLEMENTARY INFORMATION: The primary purpose of this meeting is for the GAP to receive information about potential fishery management changes regarding non-trawl rockfish conservation area management and to begin reviewing materials and preparing recommendations on groundfish matters for the September 2022 Pacific Council meeting. The GAP may also discuss other items on the Pacific Council's September agenda, particularly Pacific halibut, ecosystem, and administrative matters.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 4, 2022.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–17091 Filed 8–9–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC229]

Nominations to the American Fisheries Advisory Committee

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice; request for nominations.

SUMMARY: Nominations are being sought for appointment by the Secretary of Commerce (Secretary) to serve on the American Fisheries Advisory Committee (Committee). The Committee is responsible for making recommendations to the Secretary for financial assistance awards under the Saltonstall-Kennedy (S–K) Grant Competition under the Department of Commerce. The Committee will also make recommendations to the Secretary to assist in the development of the annual Notice of Funding Opportunities (NoFO) for submission to the S–K Grant Competition. This may include identifying the needs of the fishing communities (program priorities), establishing individual award funding limits, specifying the application review criteria and selection processes, and other sections of the NoFO as appropriate and allowable. Nominees should have demonstrable experience in one or more of the following areas of expertise, and in as many seafood species as possible: seafood harvesting or processing; recreational or commercial fishing; growing seafood; fisheries science; and/or food distribution, marketing, retail, or food service. Nominees must be able to fulfill the time commitments required for up to two annual meetings. It is anticipated that meetings will be in person, rotating

between regions and possibly lasting up to four business days, subject to the time needs of each meeting. Individuals selected to initially serve on the Committee will serve staggered terms of two, three, and four years. Terms of all future Committee members will be for three years and may not exceed more than two consecutive terms if re-appointed.

DATES: Nominations must have an email date stamp on or before September 24, 2022.

ADDRESSES: Nominations should be submitted by email to: *nmfs.afac.nominations@noaa.gov,* or by mail to: Clifford Cosgrove, Saltonstall-Kennedy National Program Manager, NMFS Office of Management and Budget, 1315 East-West Highway, Rm #14456, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Please visit *https://www.fisheries.noaa.gov/national/funding-and-financial-services/saltonstall-kennedy-research-and-development-program,* or contact Cliff Cosgrove, Saltonstall-Kennedy National Program Manager, NMFS Office of Management and Budget, by phone, at (301)427–8736, or email, at: *nmfs.afac.nominations@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Committee was created from Public Law 117–121 signed on May 12, 2022. The Committee meets no more than twice annually and membership is comprised of 22 individuals appointed by the Secretary with the following geographic representation: Region 1 consisting of Alaska, Hawaii, the Commonwealth of the Northern Mariana Islands, and the Territories of Guam and American Samoa; Region 2 consisting of Maine, New Hampshire, Massachusetts, Rhode Island, and Connecticut; Region 3 consisting of Texas, Alabama, Louisiana, Mississippi, Florida, Arkansas, Puerto Rico, and the Territory of the Virgin Islands of the United States; Region 4 consisting of California, Washington, Oregon, and Idaho; Region 5 consisting of New Jersey, New York, Delaware, Maryland, Virginia, North Carolina, South Carolina, and Georgia; and Region 6 consisting of Michigan, Minnesota, Wisconsin, Illinois, Indiana, Ohio, and Pennsylvania. Membership for each region will be composed of highly qualified, diverse individuals with experience in one or more of the following areas of expertise, and in as many seafood species as possible: seafood harvesting or processing; recreational or commercial fishing; growing seafood; fisheries science; and/or food distribution, marketing, retail, or food service.

Four at-large members shall also be appointed by the Secretary as follows: one individual with experience in food distribution, marketing, retail, or food service; one individual with experience in the recreational fishing industry supply chain, such as fishers, manufacturers, retailers, and distributors; one individual with experience in the commercial fishing industry supply chain, such as fishers, manufacturers, retailers, and distributors; and one individual who is an employee of NMFS with expertise in fisheries research.

Committee membership is voluntary and, except for reimbursable travel and related expenses per federal travel regulations, service is without compensation.

Each nominee must submit a cover letter and a resume/curriculum vitae (CV) in PDF format. The cover letter shall include a brief statement as to their interest in serving on the Committee and their qualifications. The resume/CV shall detail the applicant's contact information (address, telephone number, email address) and specific qualifications/experience/expertise as referenced in Public Law 117–121. Any applicants selected for Committee membership shall be required to complete a financial disclosure/conflict of interest form. The first Committee meeting will take place within the first two weeks of December 2022.

Nominations shall be submitted by email to *nmfs.afac.nominations@noaa.gov,* and must be received by September 24, 2022 to be considered. The full text of Public Law 117–121 and other relevant documents can be viewed at the following link: *https://www.fisheries.noaa.gov/national/funding-and-financial-services/saltonstall-kennedy-research-and-development-program*

Dated: August 3, 2022.

Daniel A. Namur,

Financial Assistance Division Chief, National Marine Fisheries Service.

[FR Doc. 2022–17162 Filed 8–9–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF EDUCATION

National Advisory Council on Indian Education (NACIE); Meeting

AGENCY: National Advisory Council on Indian Education (NACIE), U.S. Department of Education.

ACTION: Notice of an open meeting.

SUMMARY: This notice sets forth the agenda, time, and instructions to access or participate in the August 24, 2022, virtual meeting of NACIE. This notice provides information about the meeting to members of the public who may be interested in attending the meeting and how to provide written comment for the meeting. Notice of this meeting is required by Section 10(a)(2) of the Federal Advisory Committee Act (FACA).

DATES: The NACIE open virtual meeting will be held on August 24, 2022 from 1:00–4:30 p.m. (EST).

FOR FURTHER INFORMATION CONTACT: Donna Sabis-Burns, Designated Federal Official, Office of Elementary and Secondary Education (OESE)/Office of Indian Education (OIE), U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. Telephone: 202–213–9014, Email: *Donna.Sabis-Burns@ed.gov*.

SUPPLEMENTARY INFORMATION:

Statutory Authority and Function: NACIE is authorized by Section 6141 of the Elementary and Secondary Education Act of 1965 (ESEA), as amended (20 U.S.C. 7471). The work of NACIE was expanded per Executive Order 14049. In accordance with Section 6141 of the ESEA, NACIE shall advise the Secretary of Education and the Secretary of Interior on the funding and administration (including the development of regulations and administrative policies and practices) of any program, including any program established under Title VI, Part A of the ESEA, with respect to which the Secretary of Education has jurisdiction and (1) that includes Indian children or adults as participants or (2) that may benefit Indian children or adults. Also in accordance with Section 6141 of the ESEA, NACIE shall make recommendations to the Secretary of Education for filling the position of Director of Indian Education whenever a vacancy occurs and shall submit to the Congress, no later than June 30 of each year, a report on its activities that includes recommendations that are considered appropriate for the improvement of Federal education programs that include Indian children or adults as participants or that may benefit Indian children or adults, and recommendations concerning the funding of any such program. In accordance with Section 3 of Executive Order 14049, NACIE shall advise the Co-Chairs of the White House Initiative on Advancing Educational Equity, Excellence and Economic Opportunity for Native Americans and Strengthening Tribal Colleges and Universities (Initiative), in consultation with the Initiative, on (1) what is needed for the development, implementation, and

coordination of educational programs and initiatives to improve educational opportunities and outcomes for Native Americans, (2) how to promote career pathways for in-demand jobs for Native American students, including registered apprenticeships as well as internships, fellowships, mentorships, and work-based learning initiatives, (3) ways to strengthen Tribal Colleges and Universities and increase their participation in agency programs, (4) how to increase public awareness of and generate solutions for the educational and training challenges and equity disparities that Native American students face and the causes of these challenges and disparities, (5) approaches to establish local and national partnerships with public, private, philanthropic, and nonprofit stakeholders to advance the policy set forth in Section 1 of Executive Order 14049, consistent with applicable law, and (6) actions for promoting, improving, and expanding educational opportunities for Native languages, traditions, and practices to be sustained through culturally responsive education. Also, in accordance with Section 3 of Executive Order 14049, NACIE and the Executive Director of the Initiative (Executive Director) shall, as appropriate and consistent with applicable law, facilitate frequent collaborations between the Initiative and Tribal Nations, Alaska Native Entities, and other Tribal organizations. Finally, in accordance with Section 3 of Executive Order 14049, NACIE shall consult with the Executive Director so that the Executive Director can address NACIE's efforts pursuant to Section 3(a) of Executive Order 14019 in the annual report of the Initiative submitted to the President.

Meeting Agenda: The purpose of this meeting is to convene NACIE to conduct the following business: (1) discussion, deliberation, and approval of the 2022 Annual Report to Congress, (2) for the Office of Indian Education (OIE) to conduct an overview and seek recommendations related to the activities of the OIE, and (3) for the Initiative to seek recommendations from NACIE.

Instructions for Accessing the Meeting: Members of the public may access the NACIE meeting via teleconference and the web. Up to 350 lines will be available on a first come, first serve basis for those who wish to join via teleconference. The dial-in listen only phone number for the meeting is 1–669–254–5252, Meeting ID: 161 715 5166. The web link to register to access the meeting via *Zoom.gov* is *https://www.zoomgov.com/meeting/register/vJIsceCuqjMuGJyzwCIWSDTJ0q5S1djwrsE.*

Public Comment: Members of the public interested in submitting written comments may do so via email to Donna Sabis-Burns at *donna.sabis-burns@ed.gov* by 11:59 p.m. on August 14, 2022. Please note, written comments should pertain to the work of NACIE.

Reasonable Accommodations: The virtual meeting is accessible to individuals with disabilities. If you will need an auxiliary aid or service for the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice no later than August 19, 2022. Although we will attempt to meet a request received after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Access to Records of the Meeting: The Department will post the official open meeting report of this meeting on the OESE website, *https://oese.ed.gov/offices/office-of-indian-education/national-advisory-council-on-indian-education-oie/*, 21 days after the meeting. Pursuant to the FACA, the public may also inspect NACIE records at the Office of Indian Education, United States Department of Education, 400 Maryland Avenue SW, Washington, DC 20202, Monday–Friday, 8:30 a.m. to 5:00 p.m. Eastern Standard Time. Please email Donna Sabis-Burns at *Donna.Sabis-Burns@ed.gov* to schedule an appointment.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You also may access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: Section 6141 of the ESEA, as amended (20 U.S.C. 7471).

Ruth Ryder,

Deputy Assistant Secretary for Policy and Programs, Office of Elementary and Secondary Education.

[FR Doc. 2022–17115 Filed 8–9–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. PP–334–1]

Application To Amend Presidential Permit; Energia Sierra Juarez U.S. Transmission, LLC

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Energia Sierra Juarez U.S. Transmission, LLC (the Applicant or ESJ) has filed an application to amend Presidential Permit No. PP–334–1. ESJ is requesting the amendment to increase the rate of electric transmission of the previously permitted facilities.

DATES: Comments, protests, or motions to intervene must be submitted on or before September 9, 2022.

ADDRESSES: Comments or motions to intervene should be addressed to Christopher Lawrence, *Christopher.Lawrence@hq.doe.gov* OE–20, 1000 Independence Ave. SW, Washington, DC 20585

FOR FURTHER INFORMATION CONTACT: Christopher Lawrence (Program Office) at (202) 586–5260 or by email to *Christopher.Lawrence@hq.doe.gov,* or James Ralph (Attorney-Adviser) at (240) 474–1140 or by email to *James.Ralph@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The construction, operation, maintenance, and connection of facilities at the international border of the United States for the transmission of electric energy between the United States and a foreign country is prohibited in the absence of a Presidential permit issued pursuant to Executive Order (E.O.) 10485, as amended by E.O. 12038.

On May 18, 2022, ESJ filed an application with the Office of Electricity of the Department of Energy (DOE), as required by regulations at 10 CFR 205.320 *et seq.,* requesting that DOE amend Presidential Permit No. PP–334 to increase the rate of transmission over ESJ's operating electric power generation tie line (ESJ Tie Line).

On August 31, 2012, DOE issued Presidential Permit No. PP–334, authorizing ESJ to construct, operate, maintain, and connect the ESJ Project

(Project). As described in PP–334, the Project is a double-circuit 230-kV electric transmission line originating at San Diego Gas and Electric Company's planned East County (ECO) Substation in San Diego County, interconnecting with the Imperial Valley-Miguel segment of the Southwest Powerlink, extending approximately 0.65 miles southward, crossing the U.S.-Mexico border near Jacumba, California. At the border, the ESJ Tie Line transitions to a generation tie line constructed and operated by Energia Sierra Juarez, S. de R. L. de C.V. (ESJ Mexico), a Mexican affiliate of ESJ, which extends approximately 1 mile farther south to an interconnection point for a wind generating facility in Mexico (ESJ Wind Project) owned and operated by ESJ Mexico.

The ESJ Tie Line commenced commercial operation in June of 2015, and ESJ has been operating the ESJ Tie Line in accordance with PP–334 since that time to transmit power from the initial phase of the ESJ Wind Project generating facilities in Mexico to the electric grid in California at the ECO Substation. The ESJ Tie Line has the thermal capacity to transmit up to 1250 megawatts (MW of electricity, corresponding to the total potential generating capacity of the ESJ Wind Project. The ESJ Wind Project was to be developed in several phases. At the time PP–334 was issued in 2012, the California Independent System Operator (CAISO) had completed a generation interconnection study only for the first 400 MW of generation from the ESJ Wind Project. As a result, PP–334 included a provision limiting the maximum non-simultaneous rate of transmission over the ESJ Tie Line to 400 MW.

Article 4 of PP–334 stated that ESJ may apply for a modification to the permit to increase the authorized rate of transmission at such time as CAISO completes interconnection studies for power generated by the ESJ Wind Project greater than 400 MW.

In accordance with Article 4 of PP–334, ESJ is now requesting a modification to the permit to increase the maximum authorized rate of transmission over the ESJ Tie Line to 700 MW based on the CAISO interconnection study for Cimarron Wind, which is expected to add another 300 MW of generation. The proposed increase in the rate of transmission requires no physical modifications to the ESJ Tie Line.

Procedural Matters: Any person may comment on this application by filing such comment at the address provided above. Each comment should be clearly marked with OE Docket No. PP–334–1. Consideration of comments is limited to those addressing the subject of the proposed amendment. Any person seeking to become a party to this proceeding must file a motion to intervene at the address provided above in accordance with Rule 214 of FERC's Rules of Practice and Procedure (18 CFR 385.214). Two copies of each comment or motion to intervene should be filed with DOE on or before the date listed above.

Additional copies of such comments and motions to intervene also should be filed directly with: Emily C. Shults, Senior Vice President—Development, Energia Sierra Juarez U.S., LLC, 488 8th Avenue, San Diego, CA 92101, *eshults@sempraglobal.com,* and

Eric J. Murdock, Partner, Hunter Andrews Kurth LLP, N 2200 Pennsylvania Ave. NW, Washington, DC 20037, *emurdock@hunton.com.*

Before a Presidential permit may be issued or amended, DOE must determine that the proposed action is in the public interest. In making that determination, DOE may consider the environmental impacts of the proposed action (*i.e.,* granting the Presidential permit or amendment, with any conditions and limitations, or denying the permit), determine the proposed project's impact on electric reliability by ascertaining whether the proposed project would adversely affect the operation of the U.S. electric power supply system under normal and contingency conditions, and weigh any other factors that it may also deem relevant to the public interest. DOE also must obtain the favorable recommendation of the Secretary of State and the Secretary of Defense before taking final action on a Presidential permit application.

This application may be reviewed or downloaded electronically at *https://www.energy.gov/oe/pending-applications.*

Signed in Washington, DC, on August 5, 2022.

Christopher Lawrence,

Management and Program Analyst, Electricity Delivery Division, Office of Electricity.

[FR Doc. 2022–17188 Filed 8–9–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2290–124]

Pacific Gas and Electric Company; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Temporary variance of license requirement.

b. *Project No.:* 2290–124.

c. *Date Filed:* July 28, 2022.

d. *Applicant:* Southern California Edison Company (licensee).

e. *Name of Project:* Kern River No. 3 Hydroelectric Project.

f. *Location:* Kern River in Kern and Tulare counties, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* James Buerkle, Southern California Edison Company, (909) 394–8983.

i. *FERC Contact:* Robert Ballantine, (202) 502–6289, *robert.ballantine@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests is 30 days from the issuance of this notice by the Commission (September 2, 2022).

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include docket number P–2290–124. Comments emailed to Commission staff are not

considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The California Department of Fish and Wildlife has notified Southern California Edison Company that operation at the Kern River Planting Base (hatchery) has temporarily changed and flow that is diverted at the Fairfield Dam to provide 35 cubic feet per second is not needed until improvements at the hatchery are completed. The licensee is requesting a variance to continue to divert 10 cubic feet per second through the hatchery supply line for fire suppression at the KR3 Powerhouse and to maintain water in the flowline to protect the water conveyance features. If granted, the variance would last until such time that the California Department of Fish and Wildlife completes repairs and requests Southern California Edison Company to provide the full 35 cfs flow to the hatchery.

l. *Locations of the Application:* The Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp*. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. Agencies may obtain copies of the application directly from the applicant. At this time, the Commission has suspended access to the Commission's Public Reference Room due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll free, (866) 208–3676 or TTY, (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* All filings must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 385.2010.

Dated: August 3, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–17127 Filed 8–9–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG22–200–000.

Applicants: Orsted Onshore North America, LLC.

Description: Sunflower Energy Center, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 8/3/22.

Accession Number: 20220803–5125.

Comment Date: 5 p.m. ET 8/24/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1427–002; ER10–2460–021; ER10–2461–022; ER10–2463–020; ER10–2466–021; ER10–2895–023; ER10–2917–023; ER10–2918–024; ER10–2920–024; ER10–2921–023; ER10–2922–023; ER10–2966–023; ER10–3167–016; ER11–2201–026; ER11–2383–019; ER11–3376–007; ER11–3377–007; ER11–3378–007; ER11–4029–020; ER12–161–025; ER12–645–026; ER12–682–022; ER12–1311–020; ER12–2068–020; ER13–17–020; ER13–203–015; ER13–1139–023; ER22–398–001; ER13–1613–016; ER13–2143–016; ER14–25–020; ER14–1964–014; ER14–2630–016; ER16–287–009; ER17–482–008; ER19–529–008; ER19–1074–008; ER19–1075–008; ER19–2429–006; ER20–1447–004; ER20–1806–004; ER22–192–002; ER22–1010–001; ER22–1019–001; ER22–1627–001.

Applicants: AM Wind Repower LLC, Powell River Energy Inc., TerraForm IWG Acquisition Holdings II, LLC, Evolugen Trading and Marketing LP, Catalyst Old River Hydroelectric Limited Partnership, Brookfield Energy Marketing US LLC, Brookfield Smoky Mountain Hydropower LP, Brookfield Renewable Energy Marketing US LLC, Brookfield Energy Marketing Inc., Brookfield Renewable Trading and Marketing LP, BREG Aggregator LLC, BIF III Holtwood LLC, Regulus Solar, LLC, BIF II Safe Harbor Holdings, LLC, Prairie Breeze Wind Energy LLC, Black Bear Development Holdings, LLC, Brookfield White Pine Hydro LLC, Mesa Wind Power LLC, Imperial Valley Solar 1, LLC, Black Bear SO, LLC, Niagara Wind Power, LLC, Blue Sky East, LLC, Stetson Holdings, LLC, Erie Wind, LLC, California Ridge Wind Energy LLC, Bishop Hill Energy LLC, Vermont Wind, LLC, South Hurlburt Wind, LLC, Horseshoe Bend Wind, LLC, North Hurlburt Wind, LLC, Safe Harbor Water Power Corporation, Evergreen Wind Power III, LLC, Black Bear Hydro Partners, LLC, Rumford Falls Hydro LLC, Hawks Nest Hydro LLC, Great Lakes Hydro America, LLC, Erie Boulevard Hydropower, L.P., Carr Street Generating Station, L.P., Brookfield Power Piney & Deep Creek LLC, Bear Swamp Power Company LLC, Stetson Wind II, LLC, Evergreen Wind Power, LLC, Canandaigua Power Partners II, LLC, Canandaigua Power Partners, LLC, Brookfield Energy Marketing LP.

Description: Notice of Change in Status of Brookfield Energy Marketing LP, et al.

Filed Date: 7/29/22.

Accession Number: 20220729–5401.

Comment Date: 5 p.m. ET 8/19/22.

Docket Numbers: ER10–1520–009; ER10–1521–009; ER10–1522–007;

ER10–2984–060; ER11–2044–039; ER12–162–033; ER13–1266–042; ER15–2211–040; ER20–2493–004; ER21–2280–003; ER22–1385–003.

Applicants: BHER Market Operations, LLC., Independence Wind Energy LLC, OTCF, LLC, MidAmerican Energy Services, LLC, CalEnergy, LLC, Bishop Hill Energy II LLC, MidAmerican Energy Company, Merrill Lynch Commodities, Inc., Occidental Chemical Corporation, Occidental Power Marketing, L.P., Occidental Power Services, Inc.

Description: Notice of Non-Material Change in Status of Occidental Power Services, Inc., et al.

Filed Date: 7/29/22.

Accession Number: 20220729–5397.

Comment Date: 5 p.m. ET 8/19/22.

Docket Numbers: ER10–1858–010; ER10–1862–035; ER10–1863–011; ER10–1865–016; ER10–1870–010; ER10–1871–011; ER10–1873–016; ER10–1875–016; ER10–1876–017; ER10–1877–009; ER10–1878–016; ER10–1883–016; ER10–1884–016; ER10–1885–016; ER10–1888–016; ER10–1889–010; ER10–1893–035; ER10–1895–010; ER10–1934–035; ER10–1938–036; ER10–1941–016; ER10–1942–033; ER10–1944–010; ER10–1947–017; ER10–2029–014; ER10–2036–013; ER10–2040–012; ER10–2041–012; ER10–2042–041; ER10–2043–012; ER10–2044–012; ER10–2051–012; ER10–2985–039; ER10–3049–040; ER10–3051–040; ER10–3260–012; ER11–4369–020; ER12–1987–014; ER12–2261–015; ER12–2645–009; ER13–1401–010; ER13–1407–012; ER14–2931–010; ER16–2218–021; ER17–696–021; ER18–1321–005; ER19–1127–006; ER20–1699–004; ER20–1939–003.

Applicants: Calpine Northeast Development, LLC, Johanna Energy Center, LLC, Calpine King City Cogen, LLC, Calpine Mid-Merit II, LLC, Calpine Energy Solutions, LLC, North American Power Business, LLC, Calpine Fore River Energy Center, LLC,CCFC Sutter Energy, LLC, Westbrook Energy Center, LLC, Pastoria Energy Facility L.L.C., Russell City Energy Company, LLC, O.L.S. Energy-Agnews, Inc., North American Power and Gas, LLC, Granite Ridge Energy, LLC, Champion Energy, LLC, Champion Energy Services, LLC, Champion Energy Marketing LLC, Calpine Bethlehem, LLC, Zion Energy LLC, Calpine Mid-Atlantic Generation, LLC, Calpine Energy Services, L.P., Calpine Mid Merit, LLC, Calpine New Jersey Generation, LLC, Calpine Vineland Solar, LLC, Calpine Mid-Atlantic Marketing, LLC, Otay Mesa Energy Center, LLC, Bethpage Energy Center 3, LLC, Calpine Construction Finance Company, L.P., Calpine Gilroy Cogen, L.P., Calpine Power America—CA, LLC,CES Marketing IX, LLC,KIAC Partners, CES Marketing X, LLC,CPN Bethpage 3rd Turbine, Inc., Creed Energy Center, LLC, Delta Energy Center, LLC, Geysers Power Company, LLC, Gilroy Energy Center, LLC, Goose Haven Energy Center, LLC, Hermiston Power, LLC, Los Esteros Critical Energy Facility, LLC, Los Medanos Energy Center LLC, Metcalf Energy Center, LLC, Morgan Energy Center, LLC, Nissequogue Cogen Partners, South Point Energy Center, LLC, Pine Bluff Energy, LLC, Power Contract Financing, L.L.C., TBG Cogen Partners.

Description: Notice of Change in Status of TBG Cogen Partners, et al.

Filed Date: 7/29/22.

Accession Number: 20220729–5400.

Comment Date: 5 p.m. ET 8/19/22.

Docket Numbers: ER10–1874–014; ER10–2721–012; ER10–2861–010; ER12–1308–013; ER13–1504–011; ER14–2140–013; ER14–2141–013; ER14–2465–015; ER14–2466–015; ER14–2939–012; ER15–632–014; ER15–634–014; ER15–1471–012; ER15–1672–011; ER15–1952–011; ER15–2728–014; ER16–711–010; ER16–915–005; ER16–2010–006; ER16–2561–006; ER19–9–008; ER19–2287–004; ER19–2294–004; ER19–2305–004.

Applicants: Valencia Power, LLC, Mesquite Power, LLC, Goal Line L.P., Mankato Energy Center II, LLC, Sunflower Wind Project, LLC, Hancock Wind, LLC, Comanche Solar PV, LLC, Pio Pico Energy Center, LLC, Maricopa West Solar PV, LLC, Pavant Solar LLC, Evergreen Wind Power II, LLC, Blue Sky West, LLC, Cottonwood Solar, LLC, CID Solar, LLC, Imperial Valley Solar Company (IVSC) 2, LLC, RE Camelot LLC, RE Columbia Two LLC, Selmer Farm, LLC, Mulberry Farm, LLC, SWG Arapahoe, LLC, Palouse Wind, LLC, Fountain Valley Power, L.L.C., El Paso Electric Company, Mankato Energy Center, LLC.

Description: Notice of Change in Status of Blue Sky West, LLC, et al.

Filed Date: 8/1/22.

Accession Number: 20220801–5298.

Comment Date: 5 p.m. ET 8/22/22.

Docket Numbers: ER15–1015–003.

Applicants: AltaGas Brush Energy Inc.

Description: Notice of Change in Status of AltaGas Brush Energy, Inc.

Filed Date: 7/29/22.

Accession Number: 20220729–5402.

Comment Date: 5 p.m. ET 8/19/22.

Docket Numbers: ER18–315–001; ER18–2178–001; ER20–1657–002; ER20–2845–003; ER20–2846–003; ER20–2847–003.

Applicants: AB Lessee, LLC, Mechanicsville Lessee, LLC, Albemarle Beach Solar, LLC, Mechanicsville Solar, LLC, Holloman Lessee, LLC, Wildwood Lessee, LLC.

Description: Notice of Change in Status of Wildwood Lessee, LLC, et al.

Filed Date: 8/1/22.

Accession Number: 20220801–5296.

Comment Date: 5 p.m. ET 8/22/22.

Docket Numbers: ER20–1927–001.

Applicants: Midcontinent Independent System Operator, Inc., Consumers Energy Company.

Description: Compliance filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35: 2022–08–04_Amendment of Consumers' Compliance on Order 864 for ADIT to be effective 1/27/2020.

Filed Date: 8/4/22.

Accession Number: 20220804–5050.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER21–281–002.

Applicants: MidAmerican Energy Company.

Description: Tariff Amendment: Amendment to Services Tariff (Docket No. ER21–281) to be effective 1/1/2021.

Filed Date: 8/3/22.

Accession Number: 20220803–5027.

Comment Date: 5 p.m. ET 8/24/22.

Docket Numbers: ER21–1349–000.

Applicants: Cleco Power LLC.

Description: Formal Challenge of the City of Alexandria, Louisiana to March 12, 2021 Annual Informational Filing by Cleco Power LLC.

Filed Date: 4/15/21.

Accession Number: 20210415–5371.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER21–2050–001.

Applicants: Midcontinent Independent System Operator, Inc., Consumers Energy Company.

Description: Tariff Amendment: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.17(b): 2022–08–04_Amended Consumers Energy Exit Filing to be effective 12/31/9998.

Filed Date: 8/4/22.

Accession Number: 20220804–5057.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER22–1303–000.

Applicants: Cleco Power LLC.

Description: Formal Challenge of City of Alexandria, Louisiana to March 14, 2022 Annual Informational Filing by Cleco Power LLC and Request for Relief from Cleco's Annual Update Calculation.

Filed Date: 4/29/22.

Accession Number: 20220429–5480.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER22–1698–003.

Applicants: EDF Spring Field WPC, LLC.

Description: Tariff Amendment: Amendment to 3 to be effective 6/28/2022.

Filed Date: 8/3/22.

Accession Number: 20220803–5114.

Comment Date: 5 p.m. ET 8/24/22.

Docket Numbers: ER22–188–001; ER22–353–001; ER22–416–001; ER22–423–001; ER22–433–001; ER22–456–001; ER22–464–001; ER22–472–001; ER22–508–001; ER22–519–001; ER22–521–001; ER22–523–001.

Applicants: Indra Power Business TX LLC, Indra Power Business VA LLC, Indra Power Business DC LLC, Indra Power Business IL LLC, Indra Power Business DE LLC, Indra Power Business MD LLC, Indra Power Business MA LLC, Indra Power Business PA, LLC, Columbia Utilities Power Business LLC, Indra Power Business NJ, LLC, Indra Power Business MI, LLC, Indra Power Business CT, LLC.

Description: Notice of Change in Status of Indra Power Business CT, LLC, et al.

Filed Date: 8/2/22.

Accession Number: 20220802–5176.

Comment Date: 5 p.m. ET 8/23/22.

Docket Numbers: ER22–2055–001.

Applicants: Black Hills Colorado Electric, LLC.

Description: Tariff Amendment: BHCOE Reponse to Deficency Letter to be effective 8/8/2022.

Filed Date: 8/4/22.

Accession Number: 20220804–5065.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER22–2089–001.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.17(b): Supplement to Origis Development (Thalmann 1 Solar & Battery) LGIA Filing to be effective 6/1/2022.

Filed Date: 8/3/22.

Accession Number: 20220803–5101.

Comment Date: 5 p.m. ET 8/24/22.

Docket Numbers: ER22–2090–001.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.17(b): Supplement to Origis Development (Thalmann 2 Solar & Battery) LGIA Filing to be effective 6/1/2022.

Filed Date: 8/3/22.

Accession Number: 20220803–5102.

Comment Date: 5 p.m. ET 8/24/22.

Docket Numbers: ER22–2596–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3749R1 WAPA and NPPD Interconnection Agreement to be effective 8/3/2022.

Filed Date: 8/4/22.

Accession Number: 20220804–5006.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER22–2597–000.

Applicants: Consumers Energy Company.

Description: Initial rate filing: Proposed Refund of ADIT per Order No. 864 to be effective 12/31/9998.

Filed Date: 8/4/22.

Accession Number: 20220804–5011.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER22–2598–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, Service Agreement No. 6574; Queue No. AE1–101 to be effective 7/12/2022.

Filed Date: 8/4/22.

Accession Number: 20220804–5012.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER22–2599–000.

Applicants: Atlantic Power and Gas LLC.

Description: Notice of Cancellation of Market Based Rate Tariff of Atlantic Power and Gas LLC.

Filed Date: 8/1/22.

Accession Number: 20220801–5299.

Comment Date: 5 p.m. ET 8/22/22.

Docket Numbers: ER22–2600–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Service Agreement No. 360, Navopache NITS Amendment No. 1 to be effective 10/5/2022.

Filed Date: 8/4/22.

Accession Number: 20220804–5058.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER22–2601–000.

Applicants: Walleye Wind, LLC.

Description: Baseline eTariff Filing: Walleye Wind, LLC Application for Market-Based Rate Authority to be effective 10/4/2022.

Filed Date: 8/4/22.

Accession Number: 20220804–5071.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER22–2602–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Cost Responsibility Agreement, SA No. 6548; Non-Queue No. NQ–171 to be effective 7/8/2022.

Filed Date: 8/4/22.

Accession Number: 20220804–5078.

Comment Date: 5 p.m. ET 8/25/22.

Docket Numbers: ER22–2603–000.

Applicants: NorthWestern Corporation.

Description: § 205(d) Rate Filing: Revisions to Reserve Energy Service Tariff to be effective 10/1/2022.

Filed Date: 8/4/22.

Accession Number: 20220804–5086.

Comment Date: 5 p.m. ET 8/25/22.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 4, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–17153 Filed 8–9–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1218–050]

Georgia Power Company; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Request for temporary variance of Article 401.

b. *Project No:* 1218–050.

c. *Date Filed:* July 27, 2022.

d. *Applicant:* Georgia Power Company (licensee).

e. *Name of Project:* Flint River Hydroelectric Project.

f. *Location:* The project is located on the Flint River, near the City of Albany, in Lee and Dougherty counties, Georgia. The project does not occupy federally owned lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Melissa Crabbe, Southern Company, 241 Ralph McGill Boulevard, NE BIN 10193, Atlanta, GA 30308–3374, (404) 506–7273, *mccrabbe@southernco.com.*

i. *FERC Contact:* Jeremy Jessup, (202) 502–6779, *Jeremy.Jessup@ferc.gov*.

j. *Deadline for filing comments, motions to intervene, and protests:* September 2, 2022.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P–1218–050. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The applicant proposes a temporary variance from the target water surface elevation requirements of Article 401 of the license (181.8 ± 0.5 feet Plant Datum which is 0.37 foot above mean sea level) to facilitate a scheduled a drawdown of the project impoundment, Lake Worth. The purpose of the drawdown is to provide for installation of new shoreline structures and maintenance of existing shoreline structures. The licensee will lower Lake Worth approximately 3.5 feet from the lower limit of the normal target elevation range, 181.3 feet, to an elevation of 177.8 ± 0.5 feet. The drawdown is scheduled to begin on September 27, 2022, and the licensee proposes to utilize a drawdown rate of one half-foot per day. The licensee anticipates reaching the target drawdown elevation of 177.8 feet on October 3, 2022 and remain at the target drawdown elevation for four weeks. The licensee plans to begin refilling Lake Worth on November 1, 2022. The licensee states that the completion of refilling the reservoir would be dependent on precipitation and the releases from the upstream Lake Blackshear Hydroelectric Project No. 659. The licensee will continue to operate to comply with Article 401 run-of-river operations requirement when it reaches the target drawdown elevation of 177.8 feet.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: August 3, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–17128 Filed 8–9–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1892–030; Project No. 1855–050; Project No. 1904–078]

Great River Hydro, LLC; Notice of Settlement Agreement and Soliciting Comments

Take notice that the following settlement agreement has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Settlement Agreement.

b. *Project Nos.:* 1892–030, 1855–050, and 1904–078.

c. *Date filed:* August 3, 2022.

d. *Applicant:* Great River Hydro, LLC (Great River).

e. *Name of Projects:* Wilder Hydroelectric Project, Bellows Falls Hydroelectric Project, and Vernon Hydroelectric Project (collectively, projects).

f. *Location:* The existing projects are located on the Connecticut River in the counties of Orange, Windham, and Windsor, Vermont and Sullivan, Cheshire, and Grafton, New Hampshire. The projects do not affect federal land.

g. *Filed Pursuant to:* Rule 602 of the Commission's Rules of Practice and Procedure, 18 CFR 385.602.

h. *Applicant Contact:* John Ragonese, FERC License Manager, Great River Hydro, LLC, 40 Pleasant Street, Suite 202, Portsmouth, NH 03801; (603) 498–2851 or *jragonese@greatriverhydro.com*.

i. *FERC Contact:* Steve Kartalia, (202) 502–6131 or *stephen.kartalia@ferc.gov.*

j. *Deadline for filing comments:* September 2, 2022. Reply comments due September 17, 2022.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters,

without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket numbers P–1892–030, P–1855–050, and P–1904–078.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. Great River filed the Settlement Agreement on behalf of itself, the U.S. Fish and Wildlife Service, the New Hampshire Fish and Game Department, and the Vermont Fish and Wildlife Department. The purpose of the Settlement Agreement is to resolve, among the signatories, issues related to fish passage associated with the issuance of any new licenses and fishway prescriptions under Section 18 of the FPA for the projects. Specifically, the Settlement Agreement includes proposed upstream and downstream fish passage facilities, fish passage studies, and fish passage operational measures. Great River requests that the Commission consider the Settlement Agreement in its environmental analyses of the proposed relicense applications, and incorporate the proposed measures into any new licenses issued.

l. A copy of the settlement agreement may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits, in the docket number field to access the document (*i.e.,* P–1892, P–1855, and P–1904). At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC Online Support.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: August 4, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–17152 Filed 8–9–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–1102–000.
Applicants: MOGAS PIPELINE LLC.
Description: Annual Report on Revenue from Penalties Subject to Crediting of MoGas Pipeline LLC.
Filed Date: 7/29/22.
Accession Number: 20220729–5395.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: RP22–1105–000.
Applicants: Anadarko US Offshore LLC, Murphy Exploration & Production Company—USA, Eni Petroleum US LLC, INPEX Americas, Inc.
Description: Joint Petition for Temporary Waiver of Capacity Release Regulations, et al. of Anadarko US Offshore LLC, et al.
Filed Date: 7/29/22.
Accession Number: 20220729–5398.
Comment Date: 5 p.m. ET 8/10/22.

Docket Numbers: RP22–1106–000.
Applicants: East Tennessee Natural Gas, LLC.
Description: § 4(d) Rate Filing: MAD Service Charge and Action Alert Penalty Filing to be effective 10/1/2022,
Filed Date: 8/3/22.
Accession Number: 20220803–5015.
Comment Date: 5 p.m. ET 8/15/22.

Docket Numbers: RP22–1107–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (SoCal August 2022) to be effective 8/3/2022.
Filed Date: 8/3/22.
Accession Number: 20220803–5037.
Comment Date: 5 p.m. ET 8/15/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP21–993–000.
Applicants: Cove Point LNG, LP.
Description: Report Filing: Cove Point—2022 Report of Operational Sales and Purchases of Gas to be effective N/A.
Filed Date: 7/29/22.
Accession Number: 20220729–5055.
Comment Date: 5 p.m. ET 8/10/22.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 4, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–17149 Filed 8–9–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 298–083]

Southern California Edison Company; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Temporary variance of license flow requirements.

b. *Project No.:* 298–083.

c. *Date Filed:* July 20, 2022.

d. *Applicant:* Southern California Edison Company (licensee).

e. *Name of Project:* Kaweah Project.

f. *Location:* The project is located on the East Fork, Marble Fork, and Middle Fork of the Kaweah River in Tulare County, California, and occupies lands of the United States administered by the Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Wayne Allen, Southern California Edison Company, 1515 Walnut Grove Avenue, Rosemead, California 91770; (626) 302–9741; *wayne.allen@sce.com.*

i. *FERC Contact:* Joy Kurtz, (202) 502–6760, *joy.kurtz@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests is September 2, 2022.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include docket number P–298–083. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee requests Commission approval through the end of 2022 for a temporary variance of the minimum flow requirements below the Kaweah No. 1 and No. 2 diversions, as required by Article 405 of the project license. The licensee states that the projected runoff is extremely low, and current runoff in the Kaweah River and East Fork Kaweah River is at the lowest level in 20 years. Being that the licensee cannot accurately forecast long-term runoff during this extreme drought event, it is proactively requesting the temporary variance to allow it to balance available instream flow with its contractual water rights obligations, should it become necessary. Should drought conditions persist and the temporary variance is implemented, the licensee would deliver the minimum amount of water necessary through the respective diversion in order to meet its contractual water rights obligations; the licensee would not generate at the respective powerhouse(s) during implementation of the variance. The licensee would only implement the variance in the event that low inflow into the diversion dam(s) impairs the ability to meet both minimum instream flow releases and domestic water supply requirements. Additionally, the licensee proposes to monitor and report flow conditions to U.S. Fish and Wildlife Service and California Department of Fish and Wildlife during the temporary variance.

l. *Locations of the Application:* The Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* All filings must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 385.2010.

Dated: August 3, 2022.

Kimberly Bose,

Secretary.

[FR Doc. 2022–17126 Filed 8–9–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2022–0683; FRL–10129–01–OGC]

Proposed Settlement, Clean Water Act Claim

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement; request for public comment.

SUMMARY: In accordance with the Environmental Protection Agency (EPA) Administrator's March 18, 2022, memorandum regarding ''Consent Decrees and Settlement Agreements to resolve Environmental Claims Against the Agency,'' notice is hereby given of a proposed settlement in *Northwest Environmental Advocates, et al.,* v. *US EPA,* No. 1:13–cv–263 (D. Idaho). On September 24, 2013, the Northwest Environmental Advocates and the Idaho Conservation League (collectively ''Plaintiffs'') filed an amended complaint against the EPA alleging, among other things, that the Agency had failed to complete its mandatory duty under the Clean Water Act (''CWA'') to prepare and publish proposed water quality standards for mercury pollution

to protect aquatic life following its disapproval of related water quality standard revisions by the State in 2008. On July 19, 2021, the Court issued a ruling concluding that, under the circumstances of this case, EPA's disapproval created a mandatory duty for the Agency to promulgate new criteria for the State. Having ruled against EPA on liability, the Court directed the parties to file briefs regarding an appropriate remedy. EPA seeks public input on a proposed stipulated order on remedy (''Proposed Order'') prior to its final decision-making to settle the remedy portion of the litigation.

DATES: Written comments on the Proposed Order must be received by September 9, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2022–0683 online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments, see the ''Additional Information About Commenting on the Proposed Settlement'' heading under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Thomas Glazer, Water Law Office (2355A), Office of General Counsel, U.S. Environmental Protection Agency; telephone: (202) 564–0908; email address: *glazer.thomas@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Settlement

On June 15, 2013, Plaintiffs filed suit in the Federal district court for the District of Idaho against the Fish and Wildlife Service and the National Marine Fisheries Service (collectively, ''the Services''). The complaint alleged that the Services unreasonably delayed or unlawfully withheld completion of Endangered Species Act (''ESA'') consultation with EPA regarding new and revised water quality standards that were submitted in 1996 and/or 1997. On September 24, 2013, Plaintiffs filed an amended complaint adding various CWA and ESA claims against EPA regarding dozens of Idaho water quality standard submissions dating back to 1994. Broadly speaking, Plaintiffs' claims fell into two categories: claims that EPA failed to consult with the Services on various water quality standard approval actions and claims that EPA failed to complete its mandatory duties under the CWA with respect to various new and revised water quality standards adopted by the State. In April 2015, the Services entered a stipulated dismissal with Plaintiffs by which they agreed to complete certain ESA obligations. This left EPA as the sole defendant in the case.

On February 28, 2019, the Court partially granted EPA's motion to dismiss a number of claims on statute of limitations grounds. On January 21, 2021, the Court entered a stipulated order of partial dismissal, which resolved all but one remaining claim against EPA: that EPA failed to act under section 303(c)(4) of the CWA to promulgate aquatic life mercury criteria following EPA's December 12, 2008, disapproval of State revisions to its existing mercury criteria. On July 19, 2021, the Court held that, under the circumstances of this case, EPA's disapproval created a mandatory duty for the Agency to promulgate new criteria for the State. *See Nw. Env't Advocs.* v. *United States Env't Prot. Agency,* 549 F. Supp. 3d 1218 (D. Idaho 2021).

The parties have negotiated a settlement framework regarding an appropriate remedy in the form of a stipulated order on remedy. Pursuant to the agreed-upon terms, EPA would sign for publication in the **Federal Register** proposed aquatic life mercury criteria for the State of Idaho within 18 months of entry of the Proposed Order with the Court. EPA would have nine months after publication to (1) determine whether ESA section 7 consultation with the Services is required and (2) initiate any such consultation. If consultation occurs, EPA would have to finalize the criteria within eight months of the conclusion of that consultation. Alternatively, if EPA determines that consultation is not required, EPA would have to notify the Plaintiffs and finalize the criteria within eight months of that determination. As part of the agreement, EPA would include in its proposal water column concentrations, or default water column values that can be modified on a case-by-case basis, if EPA determines there are sufficient data available to support this form of criteria. If EPA declines to propose water column concentrations or default water column values, then it would explain and take comment on its reasoning for not doing so. EPA's commitment to promulgate these criteria will be null and void if the State adopts and EPA approves new aquatic life mercury criteria.

For a period of thirty (30) days following the date of publication of this notice, EPA will accept written comments relating to the Proposed Order from persons who are not parties to the litigation. EPA also may hold a public hearing on whether to enter into the Proposed Order. EPA or the Department of Justice may withdraw or withhold consent to the Proposed Order if the comments received disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Clean Water Act.

II. Additional Information About Commenting on the Proposed Settlement

A. How can I get a copy of the proposed settlement?

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2022–0683) contains a copy of the Proposed Order. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

The electronic version of the public docket for this action contains a copy of the Proposed Order and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

B. How and to whom do I submit comments?

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2022–0683 via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) or other

information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Steven Neugeboren,

Associate General Counsel.

[FR Doc. 2022–17197 Filed 8–9–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID 99422]

Deletion of Items From April 5, 2022 Open Meeting

The following items were adopted by the Commission on July 31, 2022 and August 1, 2022, respectively, and deleted from the list of items scheduled for consideration at the Friday, August 5, 2022, Open Meeting. These items were previously listed in the Commission's Sunshine Notice on Friday, July 29, 2022.

5	MEDIA	*Title:* Restricted Adjudicatory Matter. *Summary:* The Commission will consider a restricted adjudicatory matter.
6	ENFORCEMENT	*Title:* Enforcement Bureau Action. *Summary:* The Commission will consider an enforcement action.

* * * * *

The meeting will be webcast with open captioning at: *www.fcc.gov/live.* Open captioning will be provided as well as a text only version on the FCC website. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530.

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500. Audio/Video coverage of the meeting will be broadcast live with open captioning over the internet from the FCC Live web page at *www.fcc.gov/live.*

Dated: August 2, 2022.

Marlene Dortch,

Secretary.

[FR Doc. 2022–17181 Filed 8–9–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1192; FR ID 100000]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before October 11, 2022. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1192.

Title: Survey of Urban Rates, DA 13–598.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 2,275 respondents; 2,275 responses.

Estimated Time per Response: 3 hours.

Frequency of Response: Annual reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 254(b).

Total Annual Burden: 6,825 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission is not requesting that respondents submit confidential information to the Commission. Also, respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: In April 2013, the Wireline Competition Bureau of the Federal Communications Commission adopted an Order (Order), in WC Docket No. 10–90; DA 13–598, 78 FR 29063, Connect America Fund. The Order adopted the form and content for a survey of urban rates for fixed voice and fixed broadband residential services for purposes of implementing various reforms adopted as part of the USF/ICC Transformation Order, 76 FR 73830, November 29, 2011. The information collected in this survey will be used to help ensure that universal service support recipients offering fixed voice and broadband services do so at reasonably comparable rates to those in urban areas. The comparability requirements are important components of the Commission's overall effort to improve accountability for the use of universal service funding. The comparability requirements will ensure that rates are reasonably comparable for voice as well as broadband service, between urban and rural, insular, and high cost areas. Rates must be reasonably comparable so that consumers in rural, insular, and high cost areas have meaningful access to these services. This Order requires a statistically valid sample of urban providers to complete a survey with information regarding the types and prices of their offerings. The Commission conducts this survey through an online reporting form accessible to those urban providers of fixed voice and broadband services that are chosen to participate.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–17183 Filed 8–9–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID 99764]

Deletion of Item From April 5, 2022 Open Meeting

The following item was adopted by the Commission on August 3, 2022, and deleted from the list of items scheduled for consideration at the Friday, August 5, 2022, Open Meeting. This item was previously listed in the Commission's Sunshine Notice on Friday, July 29, 2022.

4	INTERNATIONAL	*Title:* Amendment of Parts 2 and 25 of the Commission's Rules to Enable GSO Fixed-Satellite Service (Space-to-Earth) Operations in the 17.3–17.8 GHz Band, to Modernize Certain Rules Applicable to 17/24 GHz BSS Space Stations, and to Establish Off-Axis Uplink Power Limits for Extended Ka-Band FSS Operations (IB Docket No. 20–330); and to Enable NGSO Fixed-Satellite Service (Space-to-Earth) Operations in the 17.3–17.8 GHz Band (IB Docket No. 22–273) *Summary:* The Commission will consider a Report and Order and a Notice of Proposed Rulemaking that would adopt a coprimary allocation for geostationary satellite orbit (GSO) fixed-satellite service (FSS) operations in the space-to-Earth (downlink) direction in the 17.3–17.8 GHz band, while protecting incumbent services, and inquire into whether the Commission should expand this FSS allocation in the 17.3–17.8 GHz band to include non-geostationary orbit (NGSO) FSS operations also in the downlink direction.

* * * * *

The meeting will be webcast with open captioning at: *www.fcc.gov/live.* Open captioning will be provided as well as a text only version on the FCC website. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530.

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500. Audio/Video coverage of the meeting will be broadcast live with open captioning over the internet from the FCC Live web page at *www.fcc.gov/live.*

Dated: August 3, 2022.

Marlene Dortch,

Secretary.

[FR Doc. 2022–17182 Filed 8–9–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 012472–004.

Agreement Name: Yang Ming/COSCO Shipping Slot Exchange Agreement.

Parties: Yang Ming Marine Transport Corp., Yang Ming (UK) Ltd. and Yang Ming (Singapore) Pte. Ltd. (acting as a

single party) and COSCO Shipping Lines Co. Ltd.

Filing Party: Robert Magovern; Cozen O'Connor.

Synopsis: The Amendment adds Yang Ming (Singapore) Pte. Ltd. as a party to the Agreement. Yang Ming (Singapore) Pte. Ltd., a subsidiary of Yang Ming Marine Transport Corp., will be listed as a sub-party along with Yang Ming (UK) Ltd. (all operating as one party).

Proposed Effective Date: 7/29/2022.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1969.

Dated: August 5, 2022.

William Cody,

Secretary.

[FR Doc. 2022–17163 Filed 8–9–22; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL MARITIME COMMISSION

Notice of Intent To Terminate

The Commission gives notice that it intends to terminate the following agreement pursuant to 46 CFR 501.17(h)(2) thirty days from publication of this notice.

Agreement No.: 011918.

Agreement Name: Seaboard Marine/Frontier Lines Space Charter Agreement.

Reason for termination: Frontier Liner Services no longer registered Vessel Operating Common Carrier.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/502.

Dated: August 5, 2022.

William Cody,

Secretary.

[FR Doc. 2022–17166 Filed 8–9–22; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than September 9, 2022.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *A3 Centurion LLC, Miami, Florida;* to become a bank holding company by acquiring OUR Community Bank, Hialeah, Florida.

Board of Governors of the Federal Reserve System.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2022–17193 Filed 8–9–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single-Source Cooperative Agreement To Fund India Council of Medical Research (ICMR) and ICMR Institutions: National Institute of Virology (NIV), Pune and National Institute of Epidemiology (NIE), Chennai; Cancellation

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice; cancellation.

SUMMARY: On June 15, 2022, the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) published a document in the **Federal Register** concerning a notice of award to fund the ICMR Institutions: National Institute of Virology (NIV), Pune and National Institute of Epidemiology (NIE), Chennai. Those awards are cancelled in their entirety.

FOR FURTHER INFORMATION CONTACT: Shana Eatman, Centers for Disease Control and Prevention, 1825 Century Center, MS V18–3, Atlanta, GA 30345, Telephone: 770–488–3933, email: *DGHPNOFOs@cdc.gov*

SUPPLEMENTARY INFORMATION: On June 15, 2022, CDC published a document announcing a notice of award of a single-source cooperative agreement to fund India Council of Medical Research (ICMR) and ICMR institutions: National Institute of Virology (NIV), Pune and National Institute of Epidemiology (NIE), Chennai (87 FR 36133). On July 1, 2022, CDC published another document that announced a corrected funding amount to that amount published on June 15, 2022 (87 FR 39521).

This document announces a cancellation of the notice of award to fund the ICMR Institutions: NIV, Pune and NIE, Chennai. These awards are cancelled in their entirety. CDC still plans to fund the ICMR in the amount of $24,495,000 with an expected total funding of approximately $122,475,000.

Amount of Award: $24,495,000 in Federal Fiscal Year (FFY) 2022, with a total estimated $122,475,000 for the 5-year period of performance, subject to availability of funds. Please note, the Notice of Funding Opportunity funding strategy is as follows: $1,980,000 for Core Component 1, and $22,515,000 in Approved but Unfunded (ABU) Components for the recipient.

Dated: August 5, 2022.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–17171 Filed 8–9–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7068–N]

Announcement of the Advisory Panel on Outreach and Education (APOE) September 15, 2022 Virtual Meeting

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the APOE (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and

makes recommendations to the Secretary of the U.S. Department of Health and Human Services (HHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Health Insurance Marketplace®, Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). This meeting is open to the public.

DATES:

Meeting Date: Thursday, September 15, 2022 from 12:00 p.m to 5:00 p.m. eastern daylight time (e.d.t).

Deadline for Meeting Registration, Presentations, Special Accommodations, and Comments: Thursday, September 8, 2022 5:00 p.m. (e.d.t).

ADDRESSES:

Meeting Location: Virtual. All those who RSVP will receive the link to attend.

Presentations and Written Comments: Presentations and written comments should be submitted to: Walt Gutowski, Designated Federal Official (DFO), Office of Communications, Centers for Medicare & Medicaid Services, 200 Independence Avenue SW, Mailstop 325G HHH, Washington, DC 20201, 202–690–5742, or via email at *APOE@cms.hhs.gov.*

Registration: Persons wishing to attend this meeting must register at the website *https://www.eventbrite.com/e/apoe-september-15-2022-virtual-meeting-tickets-380357628907* or by contacting the DFO listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, by the date listed in the **DATES** section of this notice. Individuals requiring sign language interpretation or other special accommodations should contact the DFO at the address listed in this section of this notice by the date listed in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Walt Gutowski, Designated Federal Official, Office of Communications, 200 Independence Avenue SW, Mailstop 325G HHH, Washington, DC 20201, 202–690–5742, or via email at *APOE@cms.hhs.gov.*

Additional information about the APOE is available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE* Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background and Charter Renewal Information

A. Background

The Advisory Panel for Outreach and Education (APOE) (the Panel) is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended (5 U.S.C. appendix 2), which sets forth standards for the formation and use of federal advisory committees. The Panel is authorized by section 1114(f) of the Social Security Act (the Act) (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a).

The Secretary of the U.S. Department of Health and Human Services (HHS) (the Secretary) signed the charter establishing the Citizen's Advisory Panel on Medicare Education [1] (the predecessor to the APOE) on January 21, 1999 (64 FR 7899) to advise and make recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on the effective implementation of national Medicare education programs, including with respect to the Medicare+Choice (M+C) program added by the Balanced Budget Act of 1997 (Pub. L. 105–33).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) expanded the existing health plan options and benefits available under the M+C program and renamed it the Medicare Advantage (MA) program. CMS has had substantial responsibilities to provide information to Medicare beneficiaries about the range of health plan options available and better tools to evaluate these options. The successful MA program implementation required CMS to consider the views and policy input from a variety of private sector constituents and to develop a broad range of public-private partnerships.

In addition, Title I of the MMA authorized the Secretary and the Administrator of CMS (by delegation) to establish the Medicare prescription drug benefit. The drug benefit allows beneficiaries to obtain qualified prescription drug coverage. In order to effectively administer the MA program and the Medicare prescription drug benefit, we have substantial responsibilities to provide information to Medicare beneficiaries about the range of health plan options and benefits available, and to develop better tools to evaluate these plans and benefits.

The Patient Protection and Affordable Care Act (Pub. L. 111–148) and Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively referred to as the Affordable Care Act) expanded the availability of other options for health care coverage and enacted a number of changes to Medicare as well as to Medicaid and CHIP. Qualified individuals and qualified employers are now able to purchase private health insurance coverage through a competitive marketplace, called an Affordable Insurance Exchange (also called Health Insurance Marketplace® or Marketplace® [2]). In order to effectively implement and administer these changes, we must provide information to consumers, providers, and other stakeholders through education and outreach programs regarding how existing programs will change and the expanded range of health coverage options available, including private health insurance coverage through the Marketplace®. The APOE (the Panel) allows us to consider a broad range of views and information from interested audiences in connection with this effort and to identify opportunities to enhance the effectiveness of education strategies concerning the Affordable Care Act.

The scope of this Panel also includes advising on issues pertaining to the education of providers and stakeholders with respect to the Affordable Care Act and certain provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5).

On January 21, 2011, the Panel's charter was renewed and the Panel was renamed the Advisory Panel for Outreach and Education. The Panel's charter was most recently renewed on January 19, 2021, and will terminate on January 19, 2023 unless renewed by appropriate action.

B. Charter Renewal

In accordance with the January 19, 2021 charter, the APOE will advise HHS and CMS on developing and implementing education programs that support individuals who are enrolled in or eligible for Medicare, Medicaid, CHIP, or coverage available through the Health Insurance Marketplace® and other CMS programs. The scope of this FACA group also includes advising on

[1] We note that the Citizen's Advisory Panel on Medicare Education is also referred to as the Advisory Panel on Medicare Education (65 FR 4617). The name was updated in the Second Amended Charter approved on July 24, 2000.

[2] Health Insurance Marketplace® and Marketplace® are service marks of the U.S. Department of Health and Human Services.

education of providers and stakeholders with respect to health care reform and certain provisions of the HITECH Act enacted as part of the ARRA.

The charter will terminate on January 19, 2023, unless renewed by appropriate action. The APOE was chartered under 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The APOE is governed by provisions of Pub. L. 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

In accordance with the renewed charter, the APOE will advise the Secretary and the CMS Administrator concerning optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in, or eligible for, Medicare, Medicaid, the CHIP, and coverage available through the Health Insurance Marketplace® and other CMS programs.
- Enhancing the federal government's effectiveness in informing Medicare, Medicaid, CHIP, or the Health Insurance Marketplace® consumers, issuers, providers, and stakeholders, pursuant to education and outreach programs of issues regarding these programs, including the appropriate use of public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers, partners and stakeholders.
- Expanding outreach to minority and underserved communities, including racial and ethnic minorities, in the context of Medicare, Medicaid, CHIP, and the Health Insurance Marketplace® education programs and other CMS programs as designated.
- Assembling and sharing an information base of ''best practices'' for helping consumers evaluate health coverage options.
- Building and leveraging existing community infrastructures for information, counseling, and assistance.
- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices, and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under the Affordable Care Act.

The current members of the Panel as of June 23, 2022, are as follows:

- Julie Carter, Senior Federal Policy Associate, Medicare Rights Center.
- Scott Ferguson, Psychotherapist, Scott Ferguson Psychotherapy.
- Jean-Venable Robertson Goode, Professor, Department of Pharmacotherapy and Outcomes Science, School of Pharmacy, Virginia Commonwealth University.
- Ted Henson, Director of Health Center Performance and Innovation, National Association of Community Health Centers.
- Joan Ilardo, Director of Research Initiatives, Michigan State University, College of Human Medicine.
- Daisy Kim, Policy Manager, Asian & Pacific Islander American Health Forum.
- Cheri Lattimer, Executive Director, National Transitions of Care Coalition.
- Cori McMahon, Vice President, Tridiuum.
- Alan Meade, Director of Rehabilitation Services, Holston Medical Group.
- Neil Meltzer, President and CEO, LifeBridge Health.
- Michael Minor, National Director, H.O.P.E. HHS Partnership, National Baptist Convention USA, Incorporated.
- Jina Ragland, Associate State Director of Advocacy and Outreach, AARP Nebraska.
- Morgan Reed, Executive Director, Association for Competitive Technology.
- Carrie Rogers, Associate Director, Community Catalyst.
- Margot Savoy, Senior Vice President, American Academy of Family Physicians.
- Congresswoman Allyson Schwartz, Senior Advisor, FTI Consulting.
- Matthew Snider, JD, Senior Policy Analyst, Unidos US.
- Tia Whitaker, Statewide Director, Outreach and Enrollment, Pennsylvania Association of Community Health Centers.

II. Provisions of This Notice

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the September 15, 2022 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (June 23, 2022) meeting
- CMS programs, initiatives, and priorities
- An opportunity for public comment
- Meeting summary, review of recommendations, and next steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make an oral presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

III. Meeting Participation

The meeting is open to the public, but attendance is limited to registered participants. Persons wishing to attend this meeting must register at the website *https://www.eventbrite.com/e/apoe-september-15-2022-virtual-meeting-tickets-380357628907* or contact the DFO at the address or number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice. This meeting will be held virtually. Individuals who are not registered in advance will be unable to attend the meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: August 5, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–17185 Filed 8–9–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2683]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a generic clearance to collect information to support social and behavioral research used by FDA about drug products.

DATES: Either electronic or written comments on the collection of information must be submitted by October 11, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 11, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include Docket No. FDA–2016–N–2683 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910–0847—Extension

This information collection is intended to support FDA-conducted research. Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decision-making processes and communications that affect various stakeholders. FDA uses the following methods to achieve these goals: (1) individual indepth interviews, (2) general public focus group interviews, (3) intercept interviews, (4) self-administered surveys, (5) gatekeeper surveys, and (6) focus group interviews. These methods serve the narrowly defined need for direct and informal opinion on a specific topic and serve as a qualitative and quantitative research tool having two major purposes:

- Obtaining useful information for the development of variables and measures for formulating the basic objectives of social and behavioral research and
- successfully communicating and addressing behavioral changes with intended audiences to assess the potential effectiveness of FDA communications, behavioral interventions, and other materials.

While FDA will use these methods to test and refine its ideas and help develop communication and behavioral strategies research, the Agency will generally conduct further research before making important decisions (such as adopting new policies and allocating or redirecting significant resources to support these policies).

FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner, and any other Centers will use this mechanism to test communications and social and behavioral methods about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions, beliefs, attitudes, behaviors, and use of drug and biological products and related materials. These subjects include social and behavioral research, decision-making processes, and communication and behavioral change strategies.

Annually, FDA projects about 25 social and behavioral studies using the variety of test methods listed in this document. FDA is revising this burden to account for the number of studies we have received in the last 3 years and to better reflect the scope of the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response (in hours)	Total hours
Interviews and Surveys	7,298	15	109,470	0.25 (15 minutes)	27,368

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, our burden estimate for this information collection reflects an overall increase of 35,886 responses with a corresponding increase of 8,972 hours. We attribute this adjustment to an increase in the funding in specific areas, particularly substance abuse (for example, opioids and stimulants) and COVID–19.

Dated: August 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17155 Filed 8–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1393]

Agency Information Collection Activities; Proposed Collection; Comment Request; Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions found in our Patent Term Restoration regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by October 11, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 11, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–1393 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions—21 CFR Part 60

OMB Control Number 0910–0233—Extension

This information collection supports Agency regulations. FDA's patent extension activities are conducted under the authority of section 505(j) of the Federal, Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(j)) and the Generic Animal Drug and Patent Term Restoration Act of 1988 ((Pub. L. 100–670) (21 U.S.C. 301 et seq)). The regulations are codified in part 60 (21 CFR part 60), Patent Term Restoration. New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness review before marketing is permitted. If the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent.

In enacting section 505(j) of the FD&C Act and the Generic Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (USPTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years and is calculated by USPTO based on a statutory formula. When a patent holder submits an application for patent term extension to USPTO, USPTO requests information from FDA, including the length of the regulatory review period for the patented product. If USPTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24, revision of the length of the regulatory review period, or may petition under § 60.30 to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.''

Section 60.36(a) defines *due diligence* as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.'' As provided in § 60.30(c), a *due diligence* petition ''shall set forth sufficient facts, including dates if possible, to merit an

investigation by FDA of whether the applicant acted with due diligence.'' Upon receipt of a *due diligence* petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A *due diligence* petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40, request an informal hearing for reconsideration of the *due diligence* determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created *due diligence* petition.

During the calendar years 2019 through 2022, 15 requests for revision of the regulatory review period were submitted under § 60.24(a). In addition, a total of one *due diligence* petition was submitted under § 60.30. There have been no requests for hearings under § 60.40; however, for purposes of this information collection approval, we estimate that we may receive one submission annually.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 60—patent term restoration	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
60.24; revision of regulatory review period determinations	4	3.75	15	100	1,500
60.30; due diligence petitions	1	1	1	50	50
60.40; due diligence hearings	1	1	1	10	10
Total					1,560

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects a small decrease (-1 response) associated with submissions received under § 60.24 in previous years.

Dated: August 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17147 Filed 8–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1588]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exemptions From Substantial Equivalence Requirements for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 9, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0684. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Exemptions From Substantial Equivalence Requirements for Tobacco Products

OMB Control Number 0910–0684—Revision

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

The Consolidated Appropriations Act of 2022 (Pub. L. 117–103) (the Appropriations Act), enacted on March 15, 2022, amended the definition of the term ''tobacco product'' in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) to include products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products that were not previously subject to the FD&C Act (*e.g.,* products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act beginning on April 14, 2022, including the requirement of premarket review for new tobacco products.

The FD&C Act, as amended by the Tobacco Control Act, requires that before a new tobacco product may be introduced or delivered for introduction into interstate commerce, the new tobacco product must undergo premarket review by FDA. FDA must issue an order authorizing the commercial distribution of the new tobacco product or find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act (21 U.S.C. 387j(a)(2)(A)), before the product may be introduced into commercial distribution.

FDA has established a pathway for manufacturers to request exemptions from the substantial equivalence requirements of the FD&C Act in § 1107.1 (21 CFR 1107.1) of the Agency's regulations. As described in § 1107.1(a), FDA may exempt tobacco products that are modified by adding or deleting a tobacco additive, or

increasing or decreasing the quantity of an existing tobacco additive, from the requirement of demonstrating substantial equivalence if the Agency determines that: (1) the modification would be a minor modification of a tobacco product that can be sold under the FD&C Act; (2) a report demonstrating substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health; and (3) an exemption is otherwise appropriate.

Section 1107.1(b) states that a request for exemption under section 905(j)(3) of the FD&C Act (21 U.S.C. 387e(j)(3)) may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product and that the manufacturer must submit the request and all information supporting it to FDA. The request must be made in an electronic format that FDA can process, review, and archive (or a written request must be made by the manufacturer explaining in detail why the manufacturer cannot submit the request in an electronic format and requesting an alternative means of submission to the electronic format).

An exemption request must contain: (1) the manufacturer's address and contact information; (2) identification of the tobacco product(s); (3) a detailed explanation of the purpose for the modification; (4) a detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of the existing tobacco additive; (5) a detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the FD&C Act; (6) a detailed explanation of why a report under section 905(j)(1) of the FD&C Act intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; (7) a certification (*i.e.,* a signed statement by a responsible official of the company) summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability; (8) other information justifying an exemption; and (9) an environmental assessment (EA) under part 25 (21 CFR part 25; 42 U.S.C. 4332(2)) prepared in accordance with the requirements of § 25.40 (21 CFR 25.40)).

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement for every major Federal action that will significantly affect the quality of the human environment.

The FDA NEPA regulations are contained in part 25. All applications for exemption from substantial equivalence require the submission of an EA. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specifies the content requirements for EAs for non-excluded actions.

The information required by § 1107.1(b) is submitted to FDA so FDA can determine whether an exemption from substantial equivalence to the product is appropriate for the protection of the public health. Section 1107.1(c) states that FDA will review the information submitted and determine whether to grant or deny an exemption based on whether the criteria in section 905(j)(3) of the FD&C Act are met. FDA may request additional information if necessary, to make a determination and may consider the exemption request withdrawn if the information is not provided within the requested timeframe.

This collection of information also contains a requirement that a manufacturer submit a report (referred to as an ''abbreviated report'') at least 90 days prior to making an introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, the manufacturer must submit to FDA a report that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all the modifications are covered by exemptions granted by the Secretary under section 905(j)(3).

Description of Respondents: The respondents to this collection of information are tobacco product manufacturers defined as any person, including any repacker or relabeler, who: (1) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (2) imports a finished tobacco product for sale or distribution in the United States.

Section 1107.1(b) requires that the exemption request and supporting information be submitted in an electronic format that FDA can process, review, and archive. The exemption request and supporting information must be legible and in English. These requirements ensure that FDA can review the exemption request expeditiously and appropriately. FDA provides information on its website on how manufactures may provide electronic submissions and regulatory correspondence, such as the exemption request and supporting information, as well as the abbreviated report, to FDA (*e.g.,* information on electronic media and methods of transmission). Steps on how to prepare and the recommended structure of an exemption request and abbreviated report can be found at: *https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/exemption-substantial-equivalence.* Information on how to submit exemption requests and abbreviated reports to the CTP Portal can be found here: *https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal.*

FDA does not anticipate any need to submit an exemption request or supporting information in a non-electronic format. However, a company that is not able to submit the documentation in an electronic format may submit a written request to the Center for Tobacco Products document control center (*https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp*).

In the **Federal Register** of February 25, 2022 (87 FR 10797), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment responsive to the four information collection topics solicited was received. The comment stated that the Agency should consider making the exemption request pathway (section 905(j)(3) of the FD&C Act) more flexible for new products, devices, and technology innovations.

FDA appreciates the comment and notes that although we may consider the comment, these types of actions may necessitate guidance (as noted in the comment). Currently, we believe that the exemption pathway is providing applicants an efficient pathway to make additive changes to their products and receive a marketing order. If the Agency decides to consider revising the suggested actions, these types of actions would need to be done pursuant to separate notice and comment procedures.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section and/or activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 1107.1(b); Optional preparation of tobacco product exemption from substantial equivalence request; and § 25.40; Preparation of an environmental assessment	812	1	812	24	19,488
§ 1107.1(c); Preparation of additional information for tobacco product exemption from substantial equivalence request	150	1	150	3	450
Abbreviated report submitted to demonstrate: tobacco product is modified under section 905(j)(3) of the FD&C Act, modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)	1,217	1	1,217	2	2,434
Total					22,372

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that we will receive 812 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 19,488 hours. Since an EA is required for each § 1107.1(b) (Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request), the burden per response for EAs (12 hours) has been combined with the 12 hours for an exemption request for a total of 24 hours per response.

FDA further estimates, that we will receive 150 submissions requiring additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 450 hours.

FDA estimates that 1,217 respondents will prepare 1,217 responses and each response will take approximately 2 hours to prepare an abbreviated report, as required by section 905(j)(1)(A)(ii), for a total of 2,434 hours. The estimates reflect a decrease of 1,217 hours to account for a reduction in average response time for preparing an abbreviated report. FDA provides a recommended format for applicants in the exemption order letter that significantly reduces the burden hours for preparing the abbreviated report. Therefore, FDA now estimates that the hours for the collection of information associated with exemptions from substantial equivalence requirements total 22,372 hours.

Although there may be year-to-year variability in the absolute number of exemption requests submitted, FDA considers any trends in our analysis, and the overall number of extension requests from manufacturers of tobacco products has remained consistent. Additionally, although manufacturers of NTN products are now subject to all of the tobacco product provisions in the FD&C Act, including the need to submit premarket submissions to FDA and obtain authorization from the Agency to market their product, FDA expects to receive premarket tobacco product applications for most currently marketed NTN products. FDA does not expect to receive many exemption requests for currently marketed NTN products. Thus, no additional adjustments to the number of respondents in our burden estimate are needed for NTN products as the current estimate accounts for some year-to-year variability in the absolute number of exemption requests submitted.

Dated: August 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17184 Filed 8–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 058

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 058'' (Recognition List Number: 058), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Either electronic or written comments can be submitted on the notice at any time. These modifications to the list of recognized standards are applicable August 10, 2022.

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your

comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 058.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 058.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

An electronic copy of Recognition List Number: 058 is available on the internet at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section IV for electronic access to the searchable database for the current list of FDA-recognized consensus standards, including Recognition List Number: 058 modifications and other standards-related information. Submit written requests for a single hard copy of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 058'' to Jianchao Zeng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301–796–6580. Send one self-addressed adhesive label to assist that office in processing your request, or Fax your request to 301–847–8144.

FOR FURTHER INFORMATION CONTACT: Jianchao Zeng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301–796–6580, *CDRHStandardsStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d). Amended section 514 of the FD&C Act allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In the **Federal Register** of September 14, 2018 (83 FR 46738), FDA announced the availability of a guidance entitled ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.'' The guidance describes how FDA has implemented its standards recognition program and is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.* Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at *https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents.*

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains on its website HTML and PDF versions of the list of FDA Recognized Consensus Standards, available at *https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents.* Additional information on the Agency's Standards and Conformity Assessment Program is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.*

II. Modifications to the List of Recognized Standards, Recognition List Number: 058

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency is recognizing for use in premarket submissions and other requirements for devices. FDA is incorporating these modifications to the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA is using the term ''Recognition List Number: 058'' to identify the current modifications.

In table 1, FDA describes the following modifications: (1) the withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III, FDA lists modifications the Agency is making that involve new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 058.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Anesthesiology	
		No new entries at this time.	
		B. Biocompatibility	
2–174	2–296	ISO 10993–10 Fourth edition 2021–11 Biological evaluation of medical devices—Part 10: Tests for skin sensitization.	Withdrawn and replaced with newer version.
		C. Cardiovascular	
3–116	3–181	ISO 25539–2 Third edition 2020–09 Cardiovascular implants—Endovascular devices—Part 2: Vascular stents.	Withdraw and replaced with newer version.
3–137	3–182	ASTM F3036–21 Standard Guide for Testing Absorbable Stents	Withdrawn and replaced with newer version.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–236	4–293	ANSI/ADA Standard No. 119–2021 Manual Toothbrushes	Withdrawn and replaced with newer version.
		E. General I (Quality Systems/Risk Management) (QS/RM)	
		No new entries at this time.	
		F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)	
19–4	19–46	ANSI/AAMI ES60601–1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment—Part 1: General requirements for basic safety and essential performance (IEC 60601–1:2005, MOD) [Including Amendment 2 (2021)].	Withdrawn and replaced with newer version.
19–16	19–47	ANSI/AAMI HA60601–1–11:2015 Medical Electrical Equipment—Part 1–11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601–1–11:2015 MOD) [Including AMD 1:2021].	Withdrawn and replaced with newer version.
19–30	19–45	AIM Standard 7351731 Rev. 3.00 2021–06–04 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers—An AIM Standard.	Withdrawn and replaced with newer version.
		G. General Hospital/General Plastic Surgery (GH/GPS)	
6–174	6–475	ISO 11608–4:2022 Needle-based injection systems for medical use—Requirements and test methods—Part 4: Needle-based injection systems containing electronics.	Withdrawn and replaced with newer version.
6–275	6–476	ISO 11608–2:2022 Needle-based injection systems for medical use—Requirements and test methods—Part 2: Double-ended pen needles.	Withdrawn and replaced with newer version.
6–294	6–477	ISO 11608–3:2022 Needle-based injection systems for medical use—Requirements and test methods—Part 3: Containers and integrated fluid path.	Withdrawn and replaced with newer version.
6–341	6–478	ISO 11608–1:2022 Needle-based injection systems for medical use—Requirements and test methods—Part 1: Needle-based injection systems.	Withdrawn and replaced with newer version.
6–377	6–479	ISO 11608–5:2022 Needle-based injection systems for medical use—Requirements and test methods—Part 5: Automated functions.	Withdrawn and replaced with newer version.
		H. In Vitro Diagnostics (IVD)	
7–303	.....	CLSI M60 2nd Edition Performance Standards for Antifungal Susceptibility Testing of Yeast.	Extent of recognition.
		I. Materials	
8–336	8–583	ASTM F562–22 Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035).	Withdrawn and replaced with newer version.
8–347	8–584	ASTM F2146–22 Standard Specification for Wrought Titanium-3Aluminum-2.5Vanadium Alloy Seamless Tubing for Surgical Implant Applications (UNS R56320).	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
8–354	8–585	ASTM F1377–21 Standard Specification for Cobalt-28Chromium-6Molybdenum Powder for Medical Devices (UNS R30075, UNS R31537, and UNS R31538).	Withdrawn and replaced with newer version.
8–362	8–586	ASTM F2989–21 Standard Specification for Metal Injection Molded Unalloyed Titanium Components for Surgical Implant Applications.	Withdrawn and replaced with newer version.
8–447	8–587	ISO 5832–3 Fifth Edition 2021–11 Implants for surgery—Metallic materials—Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.	Withdrawn and replaced with newer version.
8–469	8–588	ASTM F560–22 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400).	Withdrawn and replaced with newer version.
8–471	8–589	ASTM F1925–22 Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants.	Withdrawn and replaced with newer version.
8–525	8–590	ISO/TS 17137 Third Edition 2021–09 Cardiovascular implants and extracorporeal systems—Cardiovascular absorbable implants.	Withdrawn and replaced with newer version.
J. Nanotechnology			
No new entries at this time.			
K. Neurology			
No new entries at this time.			
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
No new entries at this time.			
M. Ophthalmic			
10–110	10–131	ISO 15798 Fourth edition 2022–01 Ophthalmic implants—Ophthalmic viscosurgical devices.	Withdrawn and replaced with newer version.
N. Orthopedic			
No new entries at this time.			
O. Physical Medicine			
16–166	.....	ISO 7176–21 Second edition 2009–04–01 Wheelchairs—Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.	Extent of recognition
P. Radiology			
12–277	12–343	IEC 62127–1 Edition 2.0 2022–03 Ultrasonics—Hydrophones—Part 1: Measurement and characterization of medical ultrasonic fields.	Withdrawn and replaced with newer version.
Q. Software/Informatics			
No new entries at this time.			
R. Sterility			
14–478	14–572	ANSI/AAMI ST91:2021 Flexible and semi-rigid endoscope processing in health care facilities.	Withdrawn and replaced with newer version.
14–482	14–573	ASTM F88/F88M–21 Standard Test Method for Seal Strength of Flexible Barrier Materials.	Withdrawn and replaced with newer version.
14–496	14–574	ASTM F1608–21 Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method).	Withdrawn and replaced with newer version.
14–497	14–575	ASTM F1980–21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices.	Withdrawn and replaced with newer version.
14–499	14–576	ASTM D4169–22 Standard Practice for Performance Testing of Shipping Containers and Systems.	Withdrawn and replaced with newer version.
14–514	14–577	ISO 11737–1 Third edition 2018–01 [Including: AMD1 (2021)] Sterilization of health care products—Microbiological methods—Part 1: Determination of a population of microorganisms on product [Including: Amendment 1 (2021)].	Withdrawn and replaced with newer version.
14–515	14–578	ISO 17664–1 First edition 2021–07 Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices—Part 1: Critical and semi-critical medical devices.	Extent of Recognition. Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
S. Tissue Engineering			
No new entries at this time.			

[1] All standard titles in this table conform to the style requirements of the respective organizations.

III. Listing of New Entries

In table 2, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 058. These entries are of standards not previously recognized by FDA.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
A. Anesthesiology		
1–152	Medical electrical equipment—Part 2–87: Particular requirements for basic safety and essential performance of high-frequency ventilators.	ISO 80601–2–87 First edition 2021–04.
B. Biocompatibility		
No new entries at this time.		
C. Cardiovascular		
No new entries at this time.		
D. Dental/ENT		
No new entries at this time.		
E. General I (QS/RM)		
15–135	Medical devices—Information to be supplied by the manufacturer	ISO 20417 First edition 2021–04 Corrected version 2021–12.
F. General II (ES/EMC)		
No new entries at this time.		
G. GH/GPS		
6–480	Needle-based injection systems for medical use—requirements and test methods—Part 6: On-body delivery systems.	ISO 11608–6:2022.
6–481	General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications.	ANSI/AAMI CN27:2021.
6–482	Fluid delivery performance testing for infusion pumps	AAMI TIR101:2021.
H. IVD		
7–312	Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data	CLSI M39 5th Edition.
I. Materials		
8–591	Standard Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29108).	ASTM F2229–21.
8–592	Standard Specification for Polydioxanone Polymer Resins for Surgical Implants	ASTM F3384–21.
8–593	Implants for surgery—Hydroxyapatite—Part 6: Powders	ISO 13779–6 First edition 2015–01–15 Corrected Version 2016–09–15.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
	J. Nanotechnology	
	No new entries at this time.	
	K. Neurology	
	No new entries at this time.	
	L. OB-Gyn/G/Urology	
9–139	Colorimetry—Part 5: CIE 1976 L*u*v* colour space and u',v' uniform chromaticity scale diagram.	ISO/CIE 11664–5:2016.
	M. Ophthalmic	
	No new entries at this time.	
	N. Orthopedic	
	No new entries at this time.	
	O. Physical Medicine	
	No new entries at this time.	
	P. Radiology	
12–344	Medical electrical equipment—Medical image display systems—Part 2: Acceptance and constancy tests for medical image displays.	IEC 62563–2 Edition 1.0 2021–11.
12–345	Evaluation and routine testing in medical imaging departments—Part 3–7: Acceptance and constancy tests—Imaging performance of X-ray equipment for dental cone beam computed tomography.	IEC 61223–3–7 Edition 1.0 2021–12.
	Q. Software/Informatics	
	No new entries at this time.	
	R. Sterility	
14–579	Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices—Part 2: Non-critical medical devices.	ISO 17664–2 First edition 2021–02.
	S. Tissue Engineering	
	No new entries at this time.	

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to *CDRHStandardsStaff@fda.hhs.gov.* To be considered, such recommendations should contain, at a minimum, the information available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.*

Dated: August 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17150 Filed 8–9–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 9, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently Under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0322. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Environmental Impact Considerations

OMB Control Number 0910–0322—Revision

This information collection helps support implementation of the National Environmental Policy Act (NEPA), consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act. All applications or petitions requesting FDA action require the submission of an environmental assessment (EA) or a claim of categorical exclusion (CE). A CE applies to Agency actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or environmental impact statement (EIS). Regulations in part 25 (21 CFR part 25) set forth FDA procedures with regard to NEPA requirements (part 25, subpart A); identify actions that require the preparation of an EA (part 25, subpart B); explain CEs (part 25, subpart C); and discuss the preparation of documents (part 25, subpart D). The regulations also supplement procedural provisions of NEPA that were published by the Council on Environmental Quality (CEQ) in 40 CFR parts 1500 through 1508 and the procedures included in the ''HHS General Administration Manual, part 30: Environmental Protection'' (45 FR 76519 to 76534, November 19, 1980).

In the **Federal Register** of August 25, 2021 (86 FR 47501), we published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited. On our own initiative and for efficiency of Agency operations, we are revising the information collection to account for burden that may result from recommendations found in Agency guidance and currently approved in OMB control number 0910–0541. The guidance document entitled, ''Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' identifies, interprets, and clarifies existing requirements imposed by applicable statutes and regulations, consistent with the CEQ regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for FDA's own procedures in order to ensure full compliance with the purposes and provisions of NEPA. The guidance document is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan,* and was issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 25; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 25.40(c); actions excluded from the requirement to prepare EA or EIS:					
Center for Drug Evaluation and Research (CDER) ..	14	0.9285	13	3,400	44,200
Center for Devices and Radiological Health (CDRH)	0		0		0
Center for Biologics Evaluation and Research (CBER).	4	1	4	3,400	13,600
Center for Veterinary Medicine (CVM)	9	1	9	2,160	19,440
Center for Tobacco Products (CTP)	14	1	14	80	1,120
Center for Food Safety and Applied Nutrition (CFSAN).	57	1	57	180	10,260
Subtotal			97		88,620
Section 25.15(d); actions subject to CE:					
CDER	5,186	4.2273	21,923	8	175,384
CDRH	62	1	62	6	372
CBER	3,575	2	7,150	8	57,200
CVM	114	10	1,140	2,160	3,420
CTP	0		0		0

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR part 25; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CFSAN	51	1	51	8	408
Subtotal			30,326		236,784
Total			30,423		325,404

[1] There are no capital, or operational and maintenance costs associated with the information collection.

CDER:

Under §§ 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i) (21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i)), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for CE under § 25.30 or § 25.31, or an EA under § 25.40.

CDRH:

Under § 814.20(b)(11) (21 CFR 814.20(b)(11)), premarket approvals (PMAs) (original PMAs and supplements) must contain a claim for CE under § 25.30 or § 25.34 or an EA under § 25.40.

CBER:

Under 21 CFR 601.2(a), biologic license applications (BLAs) as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20) must contain either a claim of CE under § 25.30 or § 25.32 or an EA under § 25.40.

CVM:

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs; 21 CFR 511.1(b)(10) investigational new animal drug applications and generic investigational new animal drug applications, and 21 CFR 571.1(c) food additive petitions must contain a claim for CE under § 25.30 or § 25.32 or an EA under § 25.40.

CTP:

Under sections 905, 910, and 911 of the FD&C Act (21 U.S.C. 387e, 387j, and 387k), product applications and supplements, premarket tobacco applications (PMTAs), substantial equivalences (SEs), exemption from SEs, and modified risk tobacco product applications must contain a claim for a CE or an EA. Upon evaluation, we have concluded that the majority of the EA burden for tobacco products is accounted for in other information collections currently approved by OMB. The burden we attribute to SEs is currently approved in OMB control number 0910–0673; the burden we attribute to PMTAs is currently approved in OMB control number 0910–0768; and the burden we attribute to SE exemptions is currently approved in OMB control number 0910–0684.

CFSAN:

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for CEs listed under § 25.32(i) and (q) that the Agency has received in the past 3 years. To avoid counting the burden attributed to § 25.32(o) as zero, we have estimated the burden for this claim of CE at one respondent making one submission a year for a total of one annual submission. The burden for submitting a claim of CE is captured under § 25.15(a) and (d).

As a result of revising the information collection to include submissions made to CFSAN, it reflects an increase in burden of 108 responses and 10,668 hours annually.

Dated: August 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17154 Filed 8–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0134]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Quality Standards Act Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the Mammography Quality Standards Act.

DATES: Either electronic or written comments on the collection of information must be submitted by October 11, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 11, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0134 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Quality Standards Act Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Mammography Quality Standards Act Requirements—21 CFR part 900

OMB Control Number 0910–0309—Extension

The Mammography Quality Standards Act (Pub. L. 102–539) requires the establishment of a Federal certification and inspection program for mammography facilities; standards for accreditation and certification bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. Implementing regulations are found in part 900 (21 CFR part 900). The regulations are intended to assure safe, reliable, and accurate mammography on a nationwide level. Under the regulations, as a first step in becoming certified, mammography facilities must become accredited by an FDA-approved accreditation body (AB). This requires undergoing a review of their clinical images and providing the AB with information showing that they meet the equipment, personnel, quality assurance, and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer complaint mechanism. On the basis of this accreditation, facilities are then certified by FDA or an FDA-approved State certification agency and must prominently display their certificate. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

FDA meets with its National Mammography Quality Assurance Advisory Committee (NMQAAC) for the purposes of advising FDA's mammography program on advances in mammography technology and procedures and on appropriate quality standards for mammography facilities. NMQAAC is made up of representatives of the mammography community, consumer and industry groups, and government. The meetings are open to the public and time is allotted for public statements on issues of concern in the mammography field. The chairperson may also call upon attendees to contribute to the committee discussions.

FDA also regularly meets or holds teleconferences with its approved accreditation bodies and State certification agencies to discuss issues of mutual concern. We also engage with the Conference of State Radiation Program Directors (CRCPD), a professional organization of State agencies concerned with radiation protection. The CRCPD has established a standing Mammography Committee,

which meets with FDA mammography staff at least once a year.

Finally, in recent years, FDA mammography staff have met several times with representatives of manufacturers working on the new applications of digital technology in mammography to resolve problems preventing the making of that technology generally available. FDA mammography staff have also worked with representatives of the manufacturers to develop quality assurance manuals for full field digital mammography units.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/21 CFR section/FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]
Notification of intent to become an AB—900.3(b)(1)	0.33	1	0.33	1	1
Application for approval as an AB; full [2]—900.3(b)(3)	0.33	1	0.33	320	106
Application for approval as an AB; limited [3]—900.3(b)(3).	5	1	5	30	150
AB renewal of approval—900.3(c)	1	1	1	15	15
AB application deficiencies—900.3(d)(2)	0.1	1	0.1	30	3
AB resubmission of denied applications—900.3(d)(5)	0.1	1	0.1	30	3
Letter of intent to relinquish accreditation authority—900.3(e).	0.1	1	0.1	1	1
Summary report describing all facility assessments—900.4(f).	330	1	330	7	2,310
AB reporting to FDA; facility [4]—900.4(h)	8,718	1	8,718	1	8,718
AB reporting to FDA; AB [5]—900.4(h)	5	1	5	10	50
AB financial records—900.4(i)(2)	1	1	1	16	16
Former AB new application—900.6(c)(1)	0.1	1	0.1	60	6
Reconsideration of accreditation following appeal—900.15(d)(3)(ii).	1	1	1	2	2
Application for alternative standard—900.18(c)	2	1	2	2	4
Alternative standard amendment—900.18(e)	10	1	10	1	10
Certification agency application—900.21(b)	0.33	1	0.33	320	106
Certification agency application deficiencies—900.21(c)(2).	0.1	1	0.1	30	3
Certification electronic data transmission—900.22(h)	5	200	1,000	0.083 (5 minutes)	83
Changes to standards—900.22(i)	2	1	2	30	60
Certification agency minor deficiencies—900.24(b)	1	1	1	30	30
Appeal of adverse action taken by FDA—900.25(a)	0.2	1	0.2	16	3
Inspection fee exemption—FDA Form 3422	419	1	419	0.25 (15 minutes)	105
Total					11,785

[1] Numbers have been rounded.
[2] One time burden.
[3] Refers to accreditation bodies applying to accredit specific full-field digital mammography units.
[4] Refers to the facility component of the burden for this requirement.
[5] Refers to the AB component of the burden for this requirement.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [1]
AB transfer of facility records—900.3(f)(1)	0.1	1	0.1	0	1
Consumer complaints system; AB—900.4(g)	5	1	5	1	5
Documentation of interpreting physician initial requirements—900.12(a)(1)(i)(B)(2).	87	1	87	8	696
Documentation of interpreting physician personnel requirements—900.12(a)(4).	8,718	4	34,872	1	34,872
Permanent medical record—900.12(c)(4)	8,718	1	8,718	1	8,718
Procedures for cleaning equipment—900.12(e)(13)	8,718	52	453,336	0.083 (5 minutes)	37,627
Audit program—900.12(f)	8,718	1	8,718	16	139,488
Consumer complaints system; facility—900.12(h)(2)	8,718	2	17,436	1	17,436
Certification agency conflict of interest—900.22(a)	5	1	5	1	5
Processes for suspension and revocation of certificates—900.22(d).	5	1	5	1	5
Processes for appeals—900.22(e)	5	1	5	1	5
Processes for additional mammography review—900.22(f).	5	1	5	1	5
Processes for patient notifications—900.22(g)	3	1	3	1	3
Evaluation of certification agency—900.23	5	1	5	20	100
Appeals—900.25(b)	5	1	5	1	5

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [1]
Total					238,971

[1] Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [1]
Notification of facilities that AB relinquishes its accreditation—900.3(f)(2).	0.1	1	0.1	200	20
Clinical images; facility [2]—900.4(c), 900.11(b)(1), and 900.11(b)(2).	2,885	1	2,885	1.44	4,154
Clinical images; AB [3]—900.4(c)	5	1	5	416	2,080
Phantom images; facility [2]—900.4(d), 900.11(b)(1), and 900.11(b)(2).	2,885	1	2,885	0.72 (43 minutes)	2,077
Phantom images; AB [3]—900.4(d)	5	1	5	208	1,040
Annual equipment evaluation and survey; facility [2]—900.4(e), 900.11(b)(1), and 900.11(b)(2).	8,718	1	8,718	1	8,718
Annual equipment evaluation and survey; AB [3]—900.4(e).	5	1	5	1,730	8,650
Provisional mammography facility certificate extension application—900.11(b)(3).	0	1	0	0.5 (30 minutes)	1
Mammography facility certificate reinstatement application—900.11(c).	281	1	281	5	1,405
Lay summary of examination—900.12(c)(2)	8,718	5,085	44,331,030	0.083 (5 minutes)	3,679,475
Lay summary of examination; patient refusal [4]—900.12(c)(2).	87	1	87	0.5 (30 minutes)	44
Report of unresolved serious complaints—900.12(h)(4).	20	1	20	1	20
Information regarding compromised quality; facility [2]—900.12(j)(1).	20	1	20	200	4,000
Information regarding compromised quality; AB [3]—900.12(j)(1).	20	1	20	320	6,400
Patient notification of serious risk—900.12(j)(2)	5	1	5	100	500
Reconsideration of accreditation—900.15(c)	5	1	5	2	10
Notification of requirement to correct major deficiencies—900.24(a).	0.4	1	0.4	200	80
Notification of loss of approval; major deficiencies—900.24(a)(2).	0.15	1	0.15	100	15
Notification of probationary status—900.24(b)(1)	0.3	1	0.3	200	60
Notification of loss of approval; minor deficiencies—900.24(b)(3).	0.15	1	0.15	100	15
Total					3,718,764

[1] Total hours have been rounded.
[2] Refers to the facility component of the burden for this requirement.
[3] Refers to the AB component of the burden for this requirement.
[4] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

Respondents use the Mammography Program Reporting and Information System to submit information. Our estimated burden for the information collection reflects an overall increase of 28,664 hours and a corresponding increase of 9,137,449 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years. We do not include burden for §§ 900.12(c)(1) and (3), 900.3(f)(1), and 900.24(c) because if a certifying State had its approval withdrawn, FDA would take over certifying authority for the affected facilities. Because FDA already has all the certifying State's electronic records, we assume no additional reporting burden.

Dated: August 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17151 Filed 8–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Nursing Research.

The meeting will be open to the public as indicated below, with attendance limited to space available.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website *https://videocast.nih.gov/watch=45856.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Nursing Research.

Date: September 13, 2022.

Open: 11:00 a.m. to 3:30 p.m.

Agenda: Discussion of Program Policies and Issues.

Place: National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, One Democracy Plaza, Bethesda, MD 20892, *https://videocast.nih.gov/watch=45856* (Virtual Meeting).

Closed: 3:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate review of Applications.

Place: National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, One Democracy Plaza, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dr. Elizabeth Tarlov, Ph.D., RN, Director, Division of Extramural Science Programs (DESP), National Institute of Nursing Research, 31 Center Drive, Bethesda, MD 20892, (301) 594–1580, *elizabeth.tarlov@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.ninr.nih.gov/aboutninr/nacnr,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: August 4, 2022.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17143 Filed 8–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Resource Development Network for Longitudinal behavioral and social studies.

Date: September 6, 2022.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rajasri Roy, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–6477, *rajasri.roy@nih.gov*.

Information is also available on the Institute's/Center's home page: *www.nia.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 4, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17083 Filed 8–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of Centers of Biomedical Research Excellence (COBRE) Phase III (P30) Applications.

Date: November 10, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medicine Science, Natcher Bldg 45, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Manas Chattopadhyay, Ph.D., National Institutes of Health, 45 Center Dr, Bethesda, MD 20872, *manasc@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *www.nigms.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 4, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17084 Filed 8–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Institutional Training Program (T32) Review.

Date: October 26, 2022.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John K. Hayes, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 959, Bethesda, MD 20892, (301) 451–3398, *hayesj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health.)

Dated: August 4, 2022.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17142 Filed 8–9–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

HHS Approval of Entities That Certify Medical Review Officers

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: This notice publishes a list of the Department of Health and Human Services (HHS) approved Medical Review Officers certification entities. The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), effective on October 1, 2017, addresses the role and qualifications of Medical Review Officers (MROs) and HHS approval of entities that certify MROs.

DATES: HHS approval is effective August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Sean J. Belouin, Pharm.D., CAPT, United States Public Health Service, Senior Science Policy Advisor, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857; Telephone: (240) 276–2316; Email: *sean.belouin@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: Subpart M—Medical Review Officer (MRO), Section 13.2 of the Mandatory Guidelines, ''How are nationally recognized entities or subspecialty boards that certify MROs approved?'' states as follows: ''All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (*e.g.,* answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the internet at *http://www.samhsa.gov/workplace/drug-testing.*''

HHS has completed its review of entities that certify MROs, in accordance with requests submitted by such entities to HHS. The Assistant Secretary for Mental Health and Substance Use approves the following MRO certifying entities that offer MRO certification through examination:

American Association of Medical Review Officers (AAMRO), P.O. Box 12873, Research Triangle Park, NC 27709, Phone: (919) 489–5407, Fax: (919) 490–1010, Email: *bbrandon@aamro.com*, Website: *http://www.aamro.com/*.

Medical Review Officer Certification Council (MROCC), 3231 S. Halsted St, #167, Chicago, IL 60608, Phone: (847) 631–0599, Fax: (847) 483–1282, Email: *mrocc@mrocc.org*, Website: *http://www.mrocc.org/*.

MROPREP, 2108 N St, STE N, Sacramento, CA 95816, Phone: (669) 299–5348, Email: *support@mroprep.com*, Website: *https://www.mroprep.com/courses/mrocourse*.

Miriam E. Delphin-Rittmon,

Assistant Secretary for Mental Health and Substance Use.

[FR Doc. 2022–17156 Filed 8–9–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0113]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: MyAppointment

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until September 9, 2022.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2009–0024. All submissions received must include the OMB Control Number 1615–0113 in the body of the letter, the agency name and Docket ID USCIS–2009–0024.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at

the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on May 16, 2022, at 87 FR 29759, allowing for a 60-day public comment period. USCIS did not receive comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2009–0024. in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* MyAppointment.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* No Form Number; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The MyAppointment system allows an applicant or petitioner to schedule an interview appointment with USCIS through USCIS' internet website.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection MyAppointment is 1,043,319 and the estimated hour burden per response is .1 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 104,332 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* There is no estimated total annual cost burden associated with this collection of information, all costs are captured in the information collections that require an appointment.

Dated: August 4, 2022.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–17116 Filed 8–9–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R8–ES–2022–0027; FXES11140800000–223–FF08ECAR00]

Endangered and Threatened Wildlife and Plants; Incidental Take Permit Application; Proposed Habitat Conservation Plan Amendment and Associated Documents; County of San Diego, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the receipt of an application for an incidental take permit (ITP) under the Endangered Species Act, and a draft habitat conservation plan amendment, from San Diego Gas & Electric. We have also prepared a draft environmental assessment under the National Environmental Policy Act.

DATES: We will accept comments received or postmarked on or before September 9, 2022.

ADDRESSES:

Obtaining Documents: Electronic copies of the documents this notice announces, along with public comments received, will be available online in Docket No. FWS–R8–ES–2022–0027 at *https://www.regulations.gov.*

Submitting Comments: You may submit comments by one of the following methods:

- *Email: fw8cfwocomments@fws.gov.* Please include ''San Diego Gas & Electric HCP Amendment'' at the beginning of your comments.
- *Hardcopy:* Submit comments by U.S. mail to: Assistant Field Supervisor, Carlsbad Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2177 Salk Avenue, Suite 250, Carlsbad, CA 92008.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Snyder, Assistant Field Supervisor, Carlsbad Fish and Wildlife Office (see **ADDRESSES**); telephone: 760–431–9440. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have received an application from San Diego Gas & Electric (SDG&E) for an incidental take permit (ITP) through the year 2050 that would cover 41 species, pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*). SDG&E has prepared the *Public Review Draft San Diego Gas & Electric Company Habitat Conservation Plan Amendment 2022* (HCP amendment), which would amend their 1995 *Subregional Natural Community Conservation Plan and Habitat Conservation Plan* (subregional HCP) pursuant to section 10(a)(1)(B) of the Act. The HCP Amendment includes 41 covered species, and the applicant is requesting the authorization of incidental take of the 25 covered wildlife species that could result from activities covered under the HCP amendment. The HCP amendment

includes a conservation program to avoid, minimize, and mitigate for covered activities.

The HCP amendment also includes an eagle conservation plan (ECP) that SDG&E developed with the Service. The ECP provides the information required by the Bald and Golden Eagle Protection Act (BGEPA; 16 U.S.C. 668 and 50 CFR 22) and the Service's final rule revising the regulations that govern the Service's eagle take permit program (50 CFR 13; 50 CFR 22; and 81 FR 91494, December 16, 2016) to continue including bald eagle (*Haliaeetus leucocephalus*) and golden eagle (*Aquila chrysaetos*) as covered species under the HCP amendment.

In connection with the application, we have prepared a draft environmental assessment (draft EA) under the National Environmental Policy Act of 1967, as amended (42 U.S.C. 4321 *et seq.;* NEPA), and its implementing regulations in the Code of Federal Regulations (CFR) at 40 CFR 1506.6.

We are requesting comments on the permit application and on the draft EA.

Background

Section 9 of the Act and its implementing Federal regulations prohibit the ''take'' of animal species listed as endangered or threatened. Take is defined under the Act as to ''harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in such conduct'' (16 U.S.C. 1538). ''Harm'' includes significant habitat modification or degradation that actually kills or injures listed wildlife by significantly impairing essential behavioral patterns such as breeding, feeding, or sheltering (50 CFR 17.3). However, under section 10(a) of the Act, the Service may issue permits to authorize incidental take of listed species. ''Incidental taking'' is defined as ''any taking otherwise prohibited, if such taking is incidental to, and not the purpose of, the carrying out an otherwise lawful activity'' (50 CFR 17.3). Regulations governing incidental take permits for endangered and threatened species, respectively, are found at 50 CFR 17.22 and 50 CFR 17.32.

Proposed Action

The Service would issue an ITP to SDG&E for the amendment to its subregional HCP for certain covered activities. SDG&E has requested an ITP for 41 covered species, including 25 animals and 16 plants, of which 31 are currently listed as threatened or endangered under the Act. Implementation of the HCP amendment may result in 400 acres (ac) of permanent impacts, 210 ac of temporary impacts, and 210 ac of wildfire fuels management impacts to habitat supporting covered species. The impacts anticipated are in addition to the 400 ac of habitat impacts authorized and mitigated under ITP No. PRT–809637 for the subregional HCP. The original ITP for the subregional HCP was set to expire in 2050, and the ITP for the HCP amendment is anticipated to have the same expiration date.

Plan Area

The HCP amendment plan area has been expanded from that for the subregional HCP to include all of SDG&E's 2,815,930-ac service area in all of San Diego County and portions of Orange and Riverside Counties. The plan area includes all of SDG&E's gas and electric transmission and distribution facilities, rights-of-way, buffer lands, areas owned by SDG&E and/or subject to SDG&E easements, access routes, and those areas acquired as mitigation to offset the impacts resulting from covered activities. The total plan area includes approximately 2,021,745 ac (72 percent) of natural land cover types and 794,185 ac (28 percent) of other land cover types (*e.g.,* agriculture, disturbed habitat, eucalyptus woodland, and urban/developed).

Covered Activities

The proposed section 10 ITP would allow take of covered wildlife species resulting from covered activities in the proposed HCP amendment plan area. SDG&E is requesting incidental take authorization for covered species that could be affected by activities identified in the HCP amendment. The HCP amendment covers all SDG&E operations and maintenance (O&M), minor new construction, and wildfire fuels management that may result in take of covered species in the plan area. O&M activities occur throughout SDG&E's existing network of facilities and would occur at or near the existing facilities. Minor new construction activities include installing new or replacement structures to upgrade facilities or to extend service to new customers. Minor new construction, when in preserves or proposed preserves, is limited to 1.75 acres per project. Impacts greater than 1.75 acres from minor new construction in preserves or proposed preserves would require a minor amendment approved by the Service as described in the HCP amendment. Minor amendments are permissible without amending the underlying section 10(a)(l)(B) permit, provided that the Service determines that the changes do not (1) result in additional incidental take of/impacts to covered species not analyzed in connection with the original HCP amendment; (2) result in operations under the HCP amendment that are significantly different from those analyzed in connection with the original HCP amendment; or (3) have adverse effects on the environment that are new or significantly different from those analyzed in connection with the original HCP amendment.

Covered Species

Covered species are those species addressed in the HCP amendment for which conservation actions will be implemented and for which SDG&E is seeking an ITP. Proposed covered species include the following wildlife species that are listed as threatened (T) or endangered (E) under the Act: San Diego fairy shrimp (*Branchinecta sandiegonensis,* E), Riverside fairy shrimp (*Streptocephalus woottoni,* E), Laguna Mountains skipper (*Pyrgus ruralis lagunae,* E), Hermes copper butterfly (*Lycaena hermes,* T), arroyo toad (*Anaxyrus californicus,* E), California red-legged frog (*Rana draytonii,* E), western snowy plover (Pacific Coast Population Distinct Population Segment (DPS) [*Charadrius nivosus nivosus* (*C. alexandrinus n.*), T], western yellow-billed cuckoo (*Coccyzus americanus occidentalis,* E), southwestern willow flycatcher (*Empidonax traillii extimus,* E), coastal California gnatcatcher (*Polioptila californica californica,* T), light-footed Ridgway's (=clapper) rail [*Rallus obsoletus* (=*longirostris*) *levipes,* E], California least tern [*Sternula antillarum browni* (*Sterna a. b.*), E], least Bell's vireo (*Vireo bellii pusillus,* E), Stephens' kangaroo rat (*Dipodomys stephensi,* T), peninsular bighorn sheep (*Ovis canadensis nelson,* E), and Pacific pocket mouse (*Perognathus longimembris pacificus,* E).

The golden eagle (*Aquila chrysaetos*) and the bald eagle (*Haliaeetus leucocephalus*) are also covered species in the HCP amendment, along with other regionally sensitive wildlife species, including western spadefoot (*Spea hammondii*), western pond turtle (*Actinemys marmorata*), coast horned lizard (*Phrynosoma blainvillii*), tricolored blackbird (*Agelaius tricolor*), burrowing owl (*Athene cunicularia*), coastal cactus wren (*Campylorhynchus brunneicapillus sandiegensis*) and the Belding's savannah sparrow (*Passerculus sandwichensis beldingi*).

The definition of ''take'' in the Act does not apply to plants. However, SDG&E proposes to include federally

listed plant species in recognition of the conservation benefits provided for them under the HCP amendment. For the purposes of the HCP amendment, federally listed plant species are further included to meet regulatory obligations under section 7 of the Act. SDG&E would receive assurances for all species included on the ITP under Service's ''No Surprises'' regulations found at 50 CFR 17.22(b)(5) and 50 CFR 17.32(b)(5). The following federally listed plant species are included as covered species in the HCP amendment: San Diego thorn-mint (*Acanthomintha ilicifolia,* T), San Diego ambrosia (*Ambrosia pumila,* E), Del Mar manzanita (*Arctostaphylos glandulosa* ssp. *crassifolia,* E) Encinitas baccharis (*Baccharis vanessae,* T), thread-leaved brodiaea *(Brodiaea filifolia*), Salt marsh bird's-beak (*Chloropyron maritimum* ssp. *maritimum,* E), Orcutt's spineflower (*Chorizanthe orcuttiana,* E), Otay tarplant (*Deinandra conjugens,* T), San Diego button-celery (*Eryngium aristulatum* var. *parishii,* E), willowy monardella (*Monardella viminea,* E), spreading navarretia (*Navarretia fossalis,* T), California Orcutt grass (*Orcuttia californica,* E), San Diego mesa mint (*Pogogyne abramsii,* E), and Otay Mesa mint (*Pogogyne nudiuscula,* E).

National Environmental Policy Act Compliance

The draft EA was prepared to analyze the impacts of issuing an ITP based on the HCP amendment and to inform the public of the proposed action, alternatives, and associated impacts and disclose any irreversible commitments of resources. The proposed ITP issuance triggers the need for compliance with NEPA. The proposed action presented in the draft EA is compared to the no-action alternative. The no-action alternative represents estimated future conditions to which the proposed action's estimated future conditions can be compared.

Next Steps

We will evaluate the proposed HCP amendment and comments we receive to determine whether the permit application meets the requirements and issuance criteria under section 10(a) of the Act (16 U.S.C. 1531 *et seq.*). We will also evaluate whether issuance of a section 10 ITP would comply with section 7 of the Act by conducting an intra-Service consultation. We will use the results of this consultation, in combination with the above findings, in our final analysis to determine whether or not to issue an ITP. If the requirements and issuance criteria under section 10(a) are met, we will issue the ITP to SDG&E for incidental take of covered species.

Public Comments

If you wish to comment on the permit application, proposed HCP amendment, and associated documents, you may submit comments by any of the methods noted in the **ADDRESSES** section.

Public Availability of Comments

Before including your name, address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Scott Sobiech,

Field Supervisor, Carlsbad Fish and Wildlife Office, Carlsbad, California.

[FR Doc. 2022–17200 Filed 8–9–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS01000 L1232.0000.EA0000 LVRDNV080000 241A 20X MO# 4500163715]

Notice of Temporary Closure of Public Lands for the 2022 Rise Lantern Festival in Clark County, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure.

SUMMARY: The Las Vegas Field Office announces the temporary closure of certain public lands under its administration in Clark County, NV. This temporary closure is being made in the interest of public safety in relation to the authorized 2022 Rise Lantern Festival. This closure controls access to multiple points of entry to the festival located on the Jean Dry Lake Bed in order to minimize the risk of vehicle collisions with festival participants and workers. The temporary closure also ensures adequate time to conduct clean-up of the festival location.

DATES: The temporary closure will go into effect at 12:01 a.m. on October 7, 2022, and will remain in effect until 11:59 p.m. on October 8, 2022.

ADDRESSES: The temporary closure order and map of the closure area will be posted at the BLM Las Vegas Field Office, 4701 North Torrey Pines Drive, Las Vegas, Nevada 89130 and on the BLM website: *www.blm.gov.* These materials will also be posted at the access point of Jean Dry Lake Bed and the surrounding areas.

FOR FURTHER INFORMATION CONTACT: Kenny Kendrick, Supervisory Resource Management Specialist, (702) 515–5073, or *kkendrick@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Las Vegas Field Office announces the temporary closures of certain public lands under its administration. This action is being taken to help ensure public safety and prevent unnecessary environmental degradation during the official permitted running of the 2022 Rise Lantern Festival. The public lands affected by this closure are described as follows:

Mount Diablo Meridian, Nevada

T. 24 S., R. 60 E.,
- Secs. 20 and 21, those portions lying easterly and southerly of the easterly and southerly right-of-way boundary of State Route 604;
- Secs. 22 and 27, those portions lying westerly and southerly of the westerly and southerly right-of-way boundary of the Southern Nevada Lightweight Road;
- Sec. 28;
- Sec. 29, those portions lying easterly and southerly of the easterly and southerly right-of-way boundary of the State Route 604;
- Sec. 31, those portions of the E1/2 lying easterly and southerly of the easterly and southerly right-of-way boundary of the State Route 604, excepting NVCC–0000360;
- Sec. 32, those portions lying easterly and southerly of the easterly and southerly right-of-way boundary of the State Route 604;
- Secs. 33 and 34.

T. 25 S., R. 60 E.,
- Sec. 2, W1/2;
- Secs. 3 thru 5;
- Sec. 6, those portions lying easterly and southerly of the easterly and southerly right-of-way boundary of the State Route 604, excepting NVCC–0000360;
- Sec. 7, excepting NVCC–0000360;
- Secs. 8 thru 10;
- Sec. 11, W1/2;
- Sec. 14, W1/2;
- Secs. 15 thru 17.

The area described contains 12,030 acres, more or less, according to the BLM National PLSS CadNSDI and the official plats of the surveys of the said lands, on file with the BLM.

The temporary closures will be posted to roads leading into the public lands to notify the public of the closures for the event. The closure area includes the Jean Dry Lake Bed and is bordered by Hidden Valley to the east, Sheep Mountain to the southwest, and the right-of-way boundary of State Route 604. Under the authority of Section 303(a) of the Federal Lands Policy and Management Act of 1976 (43 U.S.C. 1733(a)), 43 CFR 8360.0–7 and 43 CFR 8364.1, the BLM will enforce the following rules in the area described above:

The entire area as listed in the legal description above is closed to all vehicles and personnel except law enforcement, emergency vehicles, event personnel, event participants, and spectators. Access routes leading to the closed area will be signed to indicate a closure ahead. No vehicle stopping or parking in the closed area except for designated parking areas will be permitted. Event participants and spectators are required to remain within designated areas only.

The following restrictions will be in effect for the duration of the closure to ensure public safety of participants and spectators. Unless otherwise authorized, the following activities within the closure area are prohibited:

- Camping.
- Possession and/or consuming any alcoholic beverage, unless the person has reached the age of 21 years.
- Discharging or use of firearms or other weapons.
- Possession and/or discharging of fireworks.
- Allowing any pet or other animal in a person's care to be unrestrained at any time. Animals must be on a leash or other restraint no longer than 3 feet.
- Operation of any vehicle including any off-highway vehicle (OHV) and golf carts within the closure area, except along designated event routes to and from entrance/exit points and parking areas, or designated event vehicles and official vehicles.
- Parking any vehicle in violation of posted restrictions, or in such a manner as to obstruct or impede normal or emergency traffic movement or the parking of other vehicles, create a safety hazard, or endanger any person, property, or feature. Vehicles so parked are subject to citation, removal, and impoundment at the owner's expense.
- Operating a vehicle through, around, or beyond a restrictive sign, recognizable barricade, fence, or traffic control barrier or device.

Signs and maps directing the public to designated spectator areas will be provided by the event sponsor.

Exceptions: Temporary closure restrictions do not apply to BLM employees, contractors, or agents engaged in official duties; any Federal, State, or local officer; member of an organized rescue or firefighting force engaged in fire, emergency, or law enforcement activities; public utility employees engaged in emergency repairs; or vehicles owned by or contracted by the United States, the State of Nevada, or Clark County. The closure restrictions also do not apply to vehicles under permit for operation by event staff, contractors, and festival participants. Authorized users must have in their possession a written permit or contract from the BLM, signed by the authorized officer.

Enforcement: Any person who violates this temporary closure may be tried before a United States Magistrate and fined in accordance with 18 U.S.C. 3571, imprisoned no more than 12 months under 43 U.S.C. 1733(a) and 43 CFR 8360.0–7, or both. In accordance with 43 CFR 8365.1–7, State or local officials may also impose penalties for violations of Nevada law.

(Authority: 43 CFR 8360.0–7 and 8364.1)

Shonna Dooman,

Field Manager—Las Vegas Field Office.

[FR Doc. 2022–17124 Filed 8–9–22; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–34306; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before July 30, 2022, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by August 25, 2022.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before July 30, 2022. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers:

DELAWARE

New Castle County

Dauneport House, 420 Old Kennett Rd., Wilmington vicinity, SG100008081

NEW YORK

Erie County

Buffalo Public School #92–PS 92, 340 Fougeron St., Buffalo, SG100008007

Niagara County

Hall Apartments, 550–552 3rd St., Niagara Falls, SG100008112

Sagamore Apartments and Shops The, 518–524, 530 Main St., Niagara Falls, SG100008113

Suffolk County

Carll House (Boundary Decrease), (Huntington Town MRA), 380 Deer Park Rd., Dix Hills, BC100008114

Crest, The (Boundary Increase), (Huntington Town MRA), 563 Asharoken Ave., Huntington, BC100008116

OHIO

Lucas County

Toledo City Market, 201–237 South Erie St., Toledo, SG100008069

PUERTO RICO

Comerio Municipality

Comerio Hydroelectric Development, PR167, Km. 3.9 to 6.0, Comerio vicinity, SG100008110

Loiza Municipality

Roberto Clemente Walker Crash Site, PR 187 km. 6, Punta Maldonado and 1.5 nautical mi. offshore in the Atlantic Ocean, Loíza vicinity, SG100008070

San Juan Municipality

Escuela Ruiz Belvis, (Early Twentieth Century Schools in Puerto Rico TR), Fernandez Juncos Ave. (formerly known as Carretera Nueva), Stop 16½, San Juan, MP100008115

VIRGINIA

Albemarle County

La Fourche, 3555 Keswick Rd., Keswick, SG100008082

Pittsylvania County

Gosney Store, North corner of jct. of VA 360E (Old Richmond Rd.) and VA 726N (Malmaison Rd.), Blairs vicinity, SG100008083

Virginia Beach Independent City

L & J Gardens Neighborhood Historic District, Northampton Blvd., Norwich Ave., Maywood Blvd., and Wesleyan Dr., Virginia Beach, SG100008084

WEST VIRGINIA

Greenbrier County

Rupert School, 253 Church St., Rupert, SG100008074

Jefferson County

Haines, Nathan, Farm, 1642 Lloyd Rd., Charles Town, SG100008071

Weirick and Weller Waterwheel, 6517 Kabletown Rd., Charles Town, SG100008072

Ohio County

North Wheeling Historic District (Boundary Increase), Inclusive of area encompassed by Northern Pkwy, Ohio R., 6th St., and bluff to the east., Wheeling, BC100008073

WISCONSIN

Dane County

Owen, Ray S. and Theo P., House, 5805 Winnequah Rd., Monona, SG100008108

Jackson County

Millston Union Church, W6647 Berry St., Millston, SG100008109

Additional documentation has been received for the following resources:

MINNESOTA

Hennepin County

Minnetonka Town Hall (Additional Documentation), 13231 Minnetonka Dr., Minnetonka, AD8600381

TENNESSEE

Blount County

Brickey, Peter, House (Additional Documentation) (Blount County MPS), Wears Valley Rd., 0.1 mi. west of Bonner Hollow Rd., Townsend vicinity, AD89000869

Coffee County

Coffee County Courthouse (Additional Documentation), Public Sq., Manchester, AD74001905

Gibson County

Gibson County Courthouse (Additional Documentation), Court Sq., Trenton, AD76001777

Grundy County

Coalmont Bank Building (Additional Documentation) (Grundy County MRA), Jct. of TN 56 and Heidenburg St., Coalmont, AD91000246

Hamilton County

Oak Grove Elementary School (Additional Documentation) 1912 South Willow St., Chattanooga, AD11000420

Henry County

White, Charles M., House (Additional Documentation) (Paris MRA) 403 Whitehall Circle, Paris, AD88001425

Loudon County

Loudon County Courthouse (Additional Documentation) Grove and Mulberry Sts., Loudon, AD75001768

Shelby County

Lee, Lt. George W., House (Additional Documentation), 563 Stephens Pl., Memphis, AD94000372

Wayne County

First Presbyterian Church of Clifton (Additional Documentation), Main St., Clifton, AD88000172

VERMONT

Caledonia County

Summer Street Historic District (Additional Documentation), (St. Johnsbury MPS) 4—88 Summer St., 17 Central St. and 11, 16, 17 and 18 Church St., St. Johnsbury, AD94000634

Nominations submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nominations and responded to the Federal Preservation Officer within 45 days of receipt of the nominations and supports listing the properties in the National Register of Historic Places.

MONTANA

Gallatin County

Shenango Work Station, Custer Gallatin NF Storm Castle Rd., Gallatin Gateway vicinity, SG100008100

NEW YORK

Erie County

Buffalo Veterans Hospital Historic District, (United States Third Generation Veterans Hospitals, 1946–1958 MPS), 3495 Bailey Ave, Buffalo, MP100008102

Authority: Section 60.13 of 36 CFR part 60

Dated: August 3, 2022.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2022–17145 Filed 8–9–22; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1298]

Certain Networking Devices, Computers, and Components Thereof and Systems Containing the Same; Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation for Good Cause; Denial of Motion To Strike as Moot; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 15) of the presiding chief administrative law judge (''CALJ''), terminating the investigation for good cause. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Benjamin S. Richards, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–5453. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on February 18, 2022, based on a complaint filed by Proven Networks, LLC of Los Angeles, CA (''Proven''). 87

FR 9382 (Feb. 18, 2022). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain networking devices, computers, and components thereof and systems containing the same by reason of infringement of claims 1–37 of U.S. Patent No. 8,687,573. *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named as respondent NetApp, Inc. of San Jose, CA (''NetApp''). *Id.* The Office of Unfair Import Investigations is not participating in the investigation. *Id.*

On May 5, 2022, NetApp moved, ''[p]ursuant to Commission Rule 210.21(a) [19 CFR 210.21(a)] . . . for termination of the instant investigation based on [Proven's] clear and unequivocal waiver of the sole basis on which Proven alleges it satisfies the domestic industry requirement.'' *Certain Networking Devices, Computers, and Components Thereof and Sys. Containing the Same,* Inv. No. 337–TA–1298, Respondent's Mot. to Terminate Based on Waiver of Domestic Indus., 1 (May 5, 2022). Proven filed a response in opposition to the motion to terminate on May 16, 2022. The CALJ held oral argument on the motion on June 1, 2022. At the outset of the argument, the CALJ characterized the pending motion as one ''to terminate the investigation for good cause.'' Tr. at 4 (EDIS Doc. ID 772805).

On July 5, 2022, the CALJ issued the subject ID granting NetApp's motion and terminating the investigation in its entirety. The ID relies on the ''good cause'' language of Commission Rule 210.21(a)(1) as the basis for granting the motion. ID at 4, 12. Substantively, the ID finds that ''Proven expressly waived its ability to rely on [third-party] Extreme's products and activities to demonstrate a domestic industry in this investigation,'' and that ''[w]ithout the ability to rely on Extreme's products and services, Proven cannot satisfy the domestic industry requirement of section 337 and no violation of section 337 can be found.'' ID at 12. The Commission has determined not to review the subject ID.

The Commission has also determined to deny as moot a motion filed by NetApp to strike Proven's untimely petition for review. Proven filed an untimely petition for review of the ID, which NetApp moved to strike. Proven's request that its petition for review be received out of time was denied by the Chair. *See* EDIS Doc. ID 776332 (July 27, 2022). As such, Proven's petition for review is not on the record and therefore NetApp's motion to strike the petition from the record is moot.

The investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on August 4, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 5, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–17196 Filed 8–9–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–668–669 and 731–TA–1565–1566 (Final)]

Urea Ammonium Nitrate Solutions From Russia and Trinidad and Tobago

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is not materially injured or threatened with material injury by reason of imports of urea ammonium nitrate solutions from Russia and Trinidad and Tobago, provided for in subheading 3102.80.00 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be subsidized by the governments of Russia and Trinidad and Tobago and to be sold in the United States at less than fair value (''LTFV'').[2]

Background

The Commission instituted these investigations effective June 30, 2021, following receipt of petitions filed with the Commission and Commerce by CF Industries Nitrogen, LLC and its subsidiaries, Terra Nitrogen, Limited Partnership and Terra International (Oklahoma) LLC, all of Deerfield, Illinois. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of urea ammonium nitrate solutions from Russia and Trinidad and Tobago were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on February 23, 2022 (87 FR 10241). The Commission conducted its hearing on June 16, 2022. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on August 4, 2022. The views of the Commission are contained in USITC Publication 5338 (August 2022), entitled *Urea Ammonium Nitrate Solutions from Russia and Trinidad and Tobago: Investigation Nos. 701–TA–668–669 and 731–TA–1565–1566 (Final).*

By order of the Commission.

Issued: August 5, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–17195 Filed 8–9–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1285]

Certain Bar Code Scanners, Mobile Computers With Bar Code Scanning Capabilities, Scan Engines, and Components Thereof; Notice of Commission Decision Not to Review an Initial Determination Terminating the Investigation on the Basis of Settlement; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 23) of the presiding administrative law judge (''ALJ''),

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 87 FR 37836 and 87 FR 37828 (June 24, 2022) and 87 FR 37831 and 87 FR 37824 (June 24, 2022).

granting a joint motion to terminate the investigation in its entirety based on settlement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–2301. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On November 4, 2021, the Commission instituted this investigation based on a complaint filed on behalf of Honeywell International Inc., Hand Held Products, Inc., and Metrologic Instruments, Inc. (collectively, ''Complainants''), all of Charlotte, North Carolina. 86 FR 60915 (Nov. 4, 2021). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain bar code scanners, mobile computers with bar code scanning capabilities, scan engines, and components thereof that infringe one of more claims of U.S. Patent Nos. 8,794,520 (''the '520 patent''); 7,568,628 (''the '628 patent''); 7,770,799 (''the '799 patent''); 9,576,169 (''the '169 patent''); and 10,721,429 (''the '429 patent''). *Id.* The complaint also alleges that a domestic industry exists or is in the process of being established. *Id.* The Commission's notice of investigation named Zebra Technologies Corporation of Lincolnshire, Illinois and Symbol Technologies, Inc. of Holtsville, New York (collectively, ''Respondents'') as respondents. *Id.* The Office of Unfair Import Investigations is participating in this investigation. *Id.*

The Commission previously terminated the investigation as to the '520 patent and certain claims of the '628, '799, '169, and '429 patents. Order No. 13 (Apr. 7, 2022), *unreviewed by* Notice (Apr. 25, 2022); Order No. 19 (May 27, 2022), *unreviewed by* Notice (June 13, 2022).

On July 11, 2022, Complainants and Respondents filed a joint motion to terminate the investigation based on a license and settlement agreement between the parties. No opposition to the motion was filed.

On July 12, 2022, the ALJ issued the subject ID (Order No. 23), granting the joint motion to terminate the investigation based on settlement. The ID finds that the motion for termination satisfies Commission Rule 210.21(b) (19 CFR 210.21(b), and that no extraordinary circumstances exist that would prevent the requested termination. No petitions for review were filed.

The Commission has determined not to review the subject ID. The investigation is terminated in its entirety.

The Commission vote for this determination took place on August 4, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 4, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–17110 Filed 8–9–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–1283]

Certain Composite Baseball and Softball Bats and Components Thereof Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation With Respect to the Last Active Respondent Based on Settlement; Request for Briefing on Remedy, Bond, and the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (the ''Commission'') has determined not to review an initial determination (''ID'') (Order No. 23) issued by the presiding administrative law judge (''ALJ'') terminating the investigation with respect to Juno Athletics LLC (''Juno''), the last active respondent, based on settlement. Juno is hereby terminated from this investigation. The Commission requests written submissions from the parties, interested government agencies, and interested persons on issues of remedy, bonding, and the public interest with respect to the respondent found in default.

FOR FURTHER INFORMATION CONTACT: Carl P. Bretscher, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2382. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket system (''EDIS'') at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 2, 2021, based on a complaint filed and supplemented by Easton Diamond Sports, LLC of Thousand Oaks, California (''Easton''). 86 FR 60468–469 (Nov. 2, 2021). The complaint alleges a violation of section 337 of the Tariff Act, as amended, 19 U.S.C. 1337, based on the importation, sale for importation, or sale in the United States after importation of certain composite baseball and softball bats and components thereof by reason of infringement of one or more asserted claims of U.S. Patent No. 6,997,826. *Id.* The complaint further alleges the existence of a domestic industry. *Id.* The Commission's notice of investigation names Juno of Aventura, Florida; Monsta Athletics LLC of Calimesa, California (''Monsta''); and Proton Sports Inc. of Scottsdale, Arizona (''Proton'') as respondents. *Id.* at 60469. The Office of Unfair Import Investigations is not a party to this investigation. *Id.*

On January 25, 2022, the Commission amended the complaint and notice of investigation to add TianChang Zhengmu Aluminum Technology Co., Ltd. of Tianching City, China (''TZA'') as a respondent. Order No. 8 (Dec. 28, 2021), *unreviewed by* Comm'n Notice (Jan. 25, 2022).

On February 16, 2022, the Commission terminated TZA from the investigation based on withdrawal of the complaint. Order No. 11 (Jan. 28, 2022), *unreviewed by* Comm'n Notice (Feb. 16, 2022).

On April 12, 2022, the Commission found respondent Proton in default. Order No. 13 (March 30, 2022), *unreviewed by* Comm'n Notice (April 12, 2022).

On July 25, 2022, the Commission terminated Monsta from the investigation based on withdrawal of the complaint. Order No. 21 (June 27, 2022), *unreviewed by* Comm'n Notice (July 25, 2022).

On July 8, 2022, Easton and Juno filed a joint motion to terminate the investigation with respect to Juno based on a settlement agreement. Easton further requested issuance of a limited exclusion order (''LEO'') against the defaulting respondent, Proton. Joint Motion to Terminate the Investigation as to Respondent Juno Athletics LLC Based on Settlement and Motion to Stay the Investigation as to Juno Athletics LLC at 3 (July 11, 2022).

On July 11, 2022, the presiding ALJ issued the subject ID granting the motion to terminate the investigation with respect to Juno. Order No. 23 (July 11, 2022). The subject ID finds that the joint motion complies with the requirements of Commission Rule 210.21(a), (b) (19 CFR 210.21(a), (b)), in that the settlement agreement completely resolves the dispute between Easton and Juno, and there are no other agreements, oral or written, express or implied, between the parties regarding the subject matter of the investigation. The ID also finds that terminating Juno serves the public interest by avoiding litigation and conserving public and private resources. The ID further finds that terminating Juno is not contrary to the public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive articles in the United States, or U.S. consumers. The ID also finds there are no extraordinary circumstances that weigh against termination. No party filed a petition for review of the subject ID.

Upon review of the subject ID, the Commission has determined not to review, and thereby adopts, the subject ID. The investigation is hereby terminated with respect to Juno.

As Juno was the last active respondent in this investigation, only Proton, who was previously found in default, remains. As noted above, Easton seeks an LEO against Proton.

In connection with the final disposition of this investigation, the statute authorizes issuance of an order that could result in the exclusion of the subject articles from entry into the United States. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (December 1994).

The statute requires the Commission to consider the effects of any remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and/or cease-and-desist order would have on: (1) the public health and welfare; (2) competitive conditions in the U.S. economy; (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation; and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's action. *See* Presidential Memorandum of July 21, 2005. 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to this investigation, interested government agencies, and any other interested parties are requested to file written submissions on the issues of remedy, the public interest, and bonding.

In its initial submission, Complainant is requested to identify the remedy sought and to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to provide the HTSUS subheadings under which the accused products are imported. Complainant is further requested to supply the names of known importers of a respondent's products at issue in this investigation. Complainant is also requested to identify and explain, from the record, articles that it contends are ''components of'' the subject products, and thus potentially covered by the proposed remedial orders, if imported separately from the subject products. *See* 86 FR 60468–469. Failure to provide this information may result in waiver of any remedy directed to ''components of'' the subject products, in the event any violation may be found.

The parties' written submissions and proposed remedial orders must be filed no later than the close of business on August 26, 2022. Reply submissions must be filed no later than the close of business on September 5, 2022. Opening submissions are limited to 30 pages. Reply submissions are limited to 25 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1283'') in a prominent place on the cover page and/or first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*) Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Commission Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b), 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All non-confidential

written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The Commission voted to approve this determination on August 4, 2022.

The authority for the Commission's determinations is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 4, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–17111 Filed 8–9–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1041]

Importer of Controlled Substances Application: Lipomed

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Lipomed has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before September 9, 2022. Such persons may also file a written request for a hearing on the application on or before September 9, 2022.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on June 13, 2022, Lipomed, 150 Cambridgepark Drive, Suite 705, Cambridge, Massachusetts 02140, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine)	7286	I

The company plans to import analytical reference standards for distribution to its customers for research and analytical purposes. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–17174 Filed 8–9–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1048]

Bulk Manufacturer of Controlled Substances Application: Cambrex Charles City

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Cambrex Charles City has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before October 11, 2022. Such persons may also file a written request for a hearing on the application on or before October 11, 2022.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on May 9, 2022, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616–3466, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Tetrahydrocannabinols	7370	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
ANPP (4-Anilino-N-phenethyl-4-piperidine).	8333	II
Phenylacetone	8501	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Methadone	9250	II
Morphine	9300	II
Oripavine	9330	II

Controlled substance	Drug code	Schedule
Thebaine	9333	II
Opium extracts	9610	II
Opium fluid extract	9620	II
Opium tincture	9630	II
Opium, powdered	9639	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Fentanyl	9801	II

The company plans to manufacture the listed controlled substances in bulk for conversion to other controlled substances and sales to its customers for dosage form development, clinical trials and use in stability qualification studies.

In reference to drug codes 7360 (Marihuana), and 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–17175 Filed 8–9–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1057]

Importer of Controlled Substances Application: VA Cooperative Studies Program

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: VA Cooperative Studies Program has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before September 9, 2022. Such persons may also file a written request for a hearing on the application on or before September 9, 2022.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on June 9, 2022, VA Cooperative Studies Program, 2401 Centre Avenue SE, Albuquerque, New Mexico 87106, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I

The company plans to import finished dosage unit products containing Tetrahydrocannabinols drug code (7370) for research and clinical trial studies. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–17177 Filed 8–9–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1066]

Importer of Controlled Substances Application: Epic Pharma, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Epic Pharma, LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before September 9, 2022. Such persons may also file a written request for a hearing on the application on or before September 9, 2022.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 19, 2022, Epic Pharma, LLC, 22715 North Conduit Avenue, Laurelton, New York 11413–3134, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Methadone	9250	II

The company plans to import the listed controlled substance for research and development purposes. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–17178 Filed 8–9–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Amendment to Consent Decree Under the Clean Water Act

On August 5, 2022, the Department of Justice lodged a proposed third amendment to a consent decree with the United States District Court for the Eastern District of Missouri in the lawsuit entitled in *United States, et al.* v. *Metropolitan St. Louis Sewer District,* Civil Action No. 4:07–CV–01120.

Under the original 2012 consent decree, the Metropolitan St. Louis Sewer District (''MSD'') agreed to undertake numerous measures to come into compliance with the Clean Water Act, including constructing three combined sewer overflow (''CSO'') storage tunnels. MSD still is in the process of complying with the 2012 decree. The proposed amendment would allow MSD to replace two of these CSO storage tunnels with one larger CSO storage tunnel to accommodate overflows from all of the outfalls related to the original two CSO storage tunnels.

The publication of this notice opens a period of public comment on the proposed amendment. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States, et al.* v. *Metropolitan St. Louis Sewer District,* D.J. Ref. No. 90–5–1–1–08111. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed amendment may be examined and downloaded at this Department of Justice website: *http://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed amendment upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check in the amount of $3.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Susan M. Akers,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2022–17180 Filed 8–9–22; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2022–0002]

National Advisory Committee on Occupational Safety and Health (NACOSH): Notice of Meeting

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of NACOSH meeting.

SUMMARY: The National Advisory Committee on Occupational Safety and Health (NACOSH) will meet on September 13, 2022. In conjunction with the committee meeting, the NACOSH Heat Injury and Illness Prevention Work Group will meet separately on September 12, 2022.

DATES:

NACOSH Work Group meeting: The NACOSH Heat Injury and Illness Prevention Work Group (Heat Work Group) will meet from 1:00 p.m. to 2:00 p.m., ET, Monday, September 12, 2022.

NACOSH meeting: NACOSH will meet from 10:00 a.m. to 4:30 p.m., ET, Tuesday, September 13, 2022.

ADDRESSES:

Submission of comments and requests to speak: Submit comments and requests to speak at the NACOSH meeting by September 6, 2022, identified by the docket number for this **Federal Register** notice (Docket No. OSHA–2022–0002), using the following method:

Electronically: Comments and requests to speak, including attachments, must be submitted electronically at *www.regulations.gov,* the Federal eRulemaking Portal. Follow the online instructions for submitting comments.

Requests for special accommodations: Submit requests for special accommodations for this NACOSH meeting by September 6, 2022, to Ms. Carla Marcellus, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone: (202) 693–1865; email: *marcellus.carla@dol.gov.*

Instructions: All submissions must include the agency name and the OSHA docket number for this **Federal Register** notice (Docket No. OSHA–2022–0002). OSHA will place comments and requests to speak, including personal information, in the public docket, which may be available online. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security numbers and birthdates.

Docket: To read or download documents in the public docket for this NACOSH meeting, go to *www.regulations.gov.* All documents in the public docket are listed in the index; however, some documents (*e.g.,* copyrighted material) are not publicly available to read or download through *www.regulations.gov.* All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Participation in the NACOSH Heat Work Group meeting: Members of the public may attend the NACOSH Heat Work Group meeting. However, any participation by the public will be in listen-only mode. OSHA is not receiving public comments or requests to speak at the Heat Work Group meeting.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

For general information about NACOSH: Ms. Lisa Long, Acting Deputy Director, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone: (202) 693–2409; email: *long.lisa@dol.gov.*

Telecommunication requirements: For additional information about the telecommunication requirements for the meeting, please contact Ms. Carla Marcellus, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone: (202) 693–1865; email: *marcellus.carla@dol.gov.*

For copies of this Federal Register Notice: Electronic copies of this **Federal**

Register notice are available at *www.regulations.gov.* This notice, as well as news releases and other relevant information, are also available at OSHA's web page at *www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

NACOSH was established by Section 7(a) of the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651, 656) to advise, consult with, and make recommendations to the Secretary of Labor and the Secretary of Health and Human Services on matters relating to the administration of the OSH Act. NACOSH is a continuing advisory committee of indefinite duration.

NACOSH operates in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2), its implementing regulations (41 CFR part 102–3), and OSHA's regulations on NACOSH (29 CFR 1912.5 and 29 CFR part 1912a).

The establishment of subcommittees and subgroups, such as the NACOSH Heat Work Group, is contemplated by both the FACA's implementing regulations and OSHA's regulations on NACOSH (see, *e.g.,* 41 CFR 102–3.135; 29 CFR 1912a.13). The Heat Work Group will operate in accordance with the FACA and these regulations.

II. Meeting Information

NACOSH Meeting

NACOSH will meet from 10:00 a.m. to 4:30 p.m., ET, Tuesday, September 13, 2022. The meeting is open to the public.

Meeting agenda: The tentative agenda for this meeting includes:

- Updates from NIOSH, OSHA's Directorate of Standards and Guidance
- Safety and Health Management Systems and establishing safety as a core value;
- Special emphasis groups;
- OSHA's Whistleblower Protection Program; and
- Report from NACOSH Heat Work Group.

NACOSH Workgroup Meetings

In conjunction with the NACOSH meeting, the NACOSH Heat Illness and Injury Prevention Work Group (Heat Work Group) will meet from 1:00 p.m. to 2:00 p.m., ET on September 12, 2022.

Public attendance at the NACOSH Committee and Workgroup meetings will be virtual only. Meeting information will be posted in the Docket (Docket No. OSHA–2022–0002) and on the NACOSH web page, *https://www.osha.gov/advisorycommittee/nacosh,* prior to the meeting.

Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice under the authority granted by 29 U.S.C. 655(b)(1) and 656(b), 5 U.S.C. App. 2, 29 CFR parts 1912 and 1912a, and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed at Washington, DC.

James S. Frederick,

Deputy Assistant Secretary for Occupational Safety and Health.

[FR Doc. 2022–17121 Filed 8–9–22; 8:45 am]

BILLING CODE 4510–26–P

NUCLEAR REGULATORY COMMISSION

698th Meeting of the Advisory Committee on Reactor Safeguards (ACRS)

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232(b)), the Advisory Committee on Reactor Safeguards (ACRS) will hold meetings on September 7–9, 2022. The Committee will be conducting meetings that will include some Members being physically present at the NRC while other Members participate remotely. Interested members of the public are encouraged to participate remotely in any open sessions via MSTeams or via phone at 301–576–2978, passcode 250611443#. A more detailed agenda including the MSTeams link may be found at the ACRS public website at *https://www.nrc.gov/reading-rm/doc-collections/acrs/agenda/index.html.* If you would like the MSTeams link forwarded to you, please contact the Designated Federal Officer as follows: *Quynh.Nguyen@nrc.gov* or *Lawrence.Burkhart@nrc.gov.*

Wednesday, September 7, 2022

1:30 p.m.–1:35 p.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

1:35 p.m.–3:30 p.m.: Proposed New Regulatory Guide (RG) 1.250, ''Dedication of Commercial-grade Digital I&C Items for Nuclear Power Plants'' (Open)—The Committee will have presentations and discussion with representatives from the NRC staff and Nuclear Energy Institute regarding the subject topic.

3:30 p.m.–4:30 p.m.: Committee Deliberation on Proposed New RG 1.250 (Open)—The Committee will deliberate regarding the subject topic.

4:30 p.m.–6:00 p.m.: SHINE Memoranda Review and Deliberation/Report Preparation (Open/Closed)—The Committee will deliberate regarding the subject topic and will continue its discussion of proposed ACRS reports. [NOTE: Pursuant to 5 U.S.C 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Thursday, September 8, 2022

1:30 p.m.–5:30 p.m.: NuScale Topical Report on Emergency Planning Zone Plume (Open/Closed)—The Committee will have presentations and discussion with representatives from the NRC staff and NuScale regarding the subject topic. [NOTE: Pursuant to 5 U.S.C 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Friday, September 9, 2022

8:30 a.m.–1:00 p.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee and Reconciliation of ACRS Comments and Recommendations/Preparation of Reports/SHINE Memoranda Review and Deliberation (Open/Closed)—The Committee will hear discussion of the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS meetings, and/or proceed to preparation of reports as determined by the Chairman. [NOTE: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]. [NOTE: Pursuant to 5 U.S.C. 552b(c)(2) and (6), a portion of this meeting may be closed to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

1:00 p.m.–5:00 p.m.: SHINE Technical Specifications and Cyber Security/Report Preparation (Open/Closed)—The Committee will have presentations and discussion with representatives from the NRC staff and SHINE regarding the subject topic and will continue its discussion of proposed ACRS reports. [NOTE: Pursuant to 5 U.S.C 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

5:00 p.m.–6:00 p.m.: SHINE Memoranda Review and Deliberations/Preparation of Reports (Open/Closed)—The Committee will deliberate regarding

the subject topic and will continue its discussion of proposed ACRS reports. [NOTE: Pursuant to 5 U.S.C 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on June 13, 2019 (84 FR 27662). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff and the Designated Federal Officer (Telephone: 301–415–5844, Email: *Quynh.Nguyen@nrc.gov*), 5 days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the cognizant ACRS staff if such rescheduling would result in major inconvenience.

An electronic copy of each presentation should be emailed to the cognizant ACRS staff at least one day before the meeting.

In accordance with Subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room (PDR) at *pdr.resource@nrc.gov,* or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System component of NRC's Agencywide Documents Access and Management System, which is accessible from the NRC website at *https://www.nrc.gov/reading-rm/adams.html* or *https://www.nrc.gov/reading-rm/doc-collections/#ACRS/.*

Dated: August 5, 2022.

Russell E. Chazell,

Federal Advisory Committee Management Officer, Office of the Secretary.

[FR Doc. 2022–17161 Filed 8–9–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0044]

Information Collection: NRC Forms 541 and 541A, Uniform Low-Level Radioactive Waste Manifest Container and Waste Description and Continuation Page

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''NRC Forms 541 and 541A, Uniform Low-Level Radioactive Waste Manifest Container and Waste Description and Continuation Page.''

DATES: Submit comments by October 11, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0044. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David C. Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. NRC, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0044 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0044. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2021–0044 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* A copy of the NRC Forms 541 and 541A and related instructions may be obtained without charge by accessing ADAMS Accession Nos. ML22132A252, ML22132A253, and ML20178A433, respectively. The draft supporting statement is available in ADAMS under Accession No. ML22132A251.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0044 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* NRC Forms 541 and 541A, Uniform Low-Level Radioactive Waste Manifest Container and Waste Description and Continuation Page.

2. *OMB approval number:* 3150–0166.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* NRC Forms 541 and 541A.

5. *How often the collection is required or requested:* NRC Form 541 and 541A, or the Agreement State equivalent forms, are used by low-level radioactive waste (LLW) shippers when LLW is shipped. NRC Form 541/541A, combined with NRC Forms 540/540A and 542/542A, are collectively referred to as the Uniform Low-Level Radioactive Waste Manifest forms. The disposal facilities and their Agreement State regulators, where applicable, use the information found on the forms to ensure waste disposal meets the requirements in part 61 of title 10 of the *Code of Federal Regulations* (10 CFR) for the protection of the public and environment. The NRC does not collect or retain data on the forms and the forms are not sent to or received by the NRC. NRC Form 541/541A and NRC Form 542/542A are (1) mailed or electronically transferred to the intended consignee prior to the shipment arriving at the consignee or (2) delivered with the waste to the consignee. NRC Form 540 and 540A are required to be with the shipment regardless of which of the above methods is chosen.

6. *Who will be required or asked to respond:* NRC Form 541 and continuation Form 541A are completed by generators, collectors, and processors of LLW intended for ultimate disposal at a licensed land disposal facility.

7. *The estimated number of annual responses:* 4,616.

8. *The estimated number of annual respondents:* 712.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 15,233.

10. *Abstract:* The completed NRC Form 541 contains information needed to satisfy the waste manifesting requirements of the NRC's 10 CFR part 20. NUREG/BR–0204, Rev. 3, contains instructions for completing NRC Forms 540, 540A, 541, 541A, 542, and 542A. The forms were originally developed by the NRC at the request of low-level waste industry groups. The forms are intended to provide uniformity and efficiency in the collection of information contained in manifests which are required to control transfers of LLW intended for disposal at a land disposal facility. However, as stated in 10 CFR part 20, appendix G, ''Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. . . .''

The NRC previously noticed the availability of revisions to the Uniform Low-Level Radioactive Waste Manifest Forms in the **Federal Register** on June 25, 2021 (86 FR 33783). The information collection contained in the current extension request does not include any material changes to the forms, except for: (1) changes to the Paperwork Reduction Act statement to indicate that licensees may use equivalent forms, and (2) the deletion of the expiration date.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.

2. Is the estimate of the number of annual responses, the number of annual respondents, and the burden of the information collection accurate? Please explain your answer.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: August 5, 2022.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2022–17168 Filed 8–9–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0069]

Information Collection: Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.''

DATES: Submit comments by October 11, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject); however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0069. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David C. Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. NRC, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the

SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0069 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0069. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2022–0069 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The draft supporting statement, burden spreadsheet, and NRC Form 755 are available in ADAMS under Accession No. ML22136A268, ML22136A213, and ML22136A264.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2022–0069 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* 10 CFR part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.
2. *OMB approval number:* 3150–0214.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Form 755, ''Advance Notification to the NRC of Shipments of Category 1 Quantities of Radioactive Material.''
5. *How often the collection is required or requested:* One time for initial compliance notifications and fingerprints for the reviewing officials; and as needed for implementation notifications, event notifications, notifications of shipments of radioactive material, and fingerprinting of new employees.
6. *Who will be required or asked to respond:* Licensees that are authorized to possess and use category 1 or category 2 quantities of radioactive material.
7. *The estimated number of annual responses:* 101,479 Responses (4,704 Reporting + 1,400 Recordkeeping + 95,375 Third-Party Disclosure).
8. *The estimated number of annual respondents:* 5,600 Respondents (1,140 Agreement State Licensees + 260 NRC licensees + 4,200 Individuals making personal history disclosures under 37.23(d)).
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 74,043 Hours (1,557 Reporting + 23,989 Recordkeeping + 48,497 Third-Party Disclosure).
10. *Abstract:* Part 37 of title 10 of the *Code of Federal Regulations* (10 CFR), contains security requirements for the use of category 1 and category 2 quantities of radioactive material. Licensees are required to: (1) Develop procedures for the implementation of the security provisions; (2) develop a security plan that describes how security is being implemented; (3) implement security measures for the protection of the radioactive material; (4) conduct training on the procedures and security plan; (5) conduct background investigations for those individuals permitted unescorted access to category 1 or category 2 quantities of radioactive material; (6) coordinate with Local Law Enforcement Agencies (LLEAs) so the LLEAs would be better prepared to respond in an emergency; and (7) conduct coordination activities before shipping category 2 radioactive material, and preplanning and coordination activities before shipping category 1 radioactive material. Licensees are required to promptly report any attempted or actual theft or diversion of the radioactive material. Licensees are required to keep copies of the security plan, procedures, background investigation records, training records, and documentation associated with implementation of the security program. The NRC uses the information required by 10 CFR part 37 to fulfill its responsibilities to respond to, investigate, and correct situations that have the potential to adversely affect public health and safety or the common defense and security.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.
2. Is the estimate of the burden of the information collection accurate? Please explain your answer.
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of

automated collection techniques or other forms of information technology?

Dated: August 5, 2022.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2022–17170 Filed 8–9–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0045]

Information Collection: NRC Forms 542 and 542A, Uniform Low-Level Radioactive Waste Manifest Index and Regional Compact Tabulation and Continuation Page

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''NRC Forms 542 and 542A, Uniform Low-Level Radioactive Waste Manifest Index and Regional Compact Tabulation and Continuation Page.''

DATES: Submit comments by October 11, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0045. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David C. Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. NRC, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0045 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0045. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2021–0045 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* A copy of the NRC Forms 542 and 542A and related instructions may be obtained without charge by accessing ADAMS Accession Nos. ML22132A261, ML22132A262, and ML20178A433, respectively. The draft supporting statement is available in ADAMS under Accession No. ML22132A260.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0045 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* NRC Forms 542 and 542A, Uniform Low-Level Radioactive Waste Manifest Index and Regional Compact Tabulation and Continuation Page.

2. *OMB approval number:* 3150–0165.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* NRC Forms 542 and 542A.

5. *How often the collection is required or requested:* NRC Form 542 and 542A, or the Agreement State equivalent forms, are used by low-level radioactive waste (LLW) collectors and processors that are shipping LLW attributed to others for disposal at a licensed land disposal facility. NRC Form 542/542A, combined with NRC Forms 540/540A and 541/541A, are collectively referred to as the Uniform Low-Level Radioactive Waste Manifest forms. The disposal facilities and their Agreement State regulators, where applicable, use the information found on the forms to ensure waste disposal meets the requirements in Part 61 of title 10 of the *Code of Federal Regulations* (10 CFR) for the protection of the public and environment. The NRC does not collect

or retain data on the forms and the forms are not sent to or received by the NRC. NRC Form 541/541A and NRC Form 542/542A are (1) mailed or electronically transferred to the intended consignee prior to the shipment arriving at the consignee or (2) delivered with the waste to the consignee. NRC Form 540 and 540A are required to be with the shipment regardless of which of the above methods is chosen.

6. *Who will be required or asked to respond:* NRC Form 542 and continuation Form 542A are completed by collectors and processors of LLW intended for ultimate disposal at a licensed land disposal facility.

7. *The estimated number of annual responses:* 623.

8. *The estimated number of annual respondents:* 71.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 467.

10. *Abstract:* The NRC Form 542, completed by LLW collectors and processors, contains information needed to satisfy the waste manifesting requirements of the NRC's 10 CFR part 20 and information on the attribution of the waste. Each waste container shipped from a waste collector or processor may contain waste from several different generators. Tracking the identity of the original waste generator becomes more complicated when the waste forms, dimensions, or packaging are changed by the waste processor. These forms are used to attribute the waste to the original generator for regional waste compact tabulation. The information provided on the NRC Form 542 permits the States and Compacts to know the original generators of LLW, as authorized by the Low-Level Radioactive Waste Policy Amendments Act of 1985, so they can ensure that waste is disposed of in the appropriate Compact.

NUREG/BR–0204, Rev. 3, contains instructions for completing NRC Forms 540, 540A, 541, 541A, 542, and 542A. The forms were originally developed by the NRC at the request of low-level waste industry groups. The forms are intended to provide uniformity and efficiency in the collection of information contained in manifests which are required to control transfers of LLW intended for disposal at a land disposal facility. However, as stated in 10 CFR part 20, Appendix G, ''Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. . . .''

The NRC previously noticed the availability of revisions to the Uniform Low-Level Radioactive Waste Manifest Forms in the **Federal Register** on June 25, 2021 (86 FR 33783). The information collection contained in the current extension request does not include any material changes to the forms, except for: (1) changes to the Paperwork Reduction Act statement to indicate that licensees may use equivalent forms, and (2) the deletion of the expiration date.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.

2. Is the estimate of the number of annual responses, the number of annual respondents, and the burden of the information collection accurate? Please explain your answer.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: August 5, 2022.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2022–17167 Filed 8–9–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0043]

Information Collection: NRC Forms 540 and 540A, Uniform Low-Level Radioactive Waste Manifest (Shipping Paper) and Continuation Page

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''NRC Forms 540 and 540A, Uniform Low-Level Radioactive Waste Manifest (Shipping Paper) and Continuation Page.''

DATES: Submit comments by October 11, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0043. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David C. Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. NRC, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0043 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0043. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2021–0043 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–

415–4737, or by email to *PDR.Resource@nrc.gov.* A copy of the NRC Forms 540 and 540A and related instructions may be obtained without charge by accessing ADAMS Accession Nos. ML22132A240, ML22132A241, and ML20178A433, respectively. The draft supporting statement is available in ADAMS under Accession No. ML22132A239.

• *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

• *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0043 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* NRC Forms 540 and 540A, Uniform Low-Level Radioactive Waste Manifest (Shipping Paper) and Continuation Page.

2. *OMB approval number:* 3150–0164.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* NRC Forms 540 and 540A.

5. *How often the collection is required or requested:* NRC Form 540 and 540A, or the Agreement State equivalent forms, are used by low-level radioactive waste (LLW) shippers when LLW is shipped. NRC Form 540/540A, combined with NRC Forms 541/541A and 542/542A, are collectively referred to as the Uniform Low-Level Radioactive Waste Manifest forms. The disposal facilities and their Agreement State regulators, where applicable, use the information found on the forms to ensure waste disposal meets the requirements in part 61 of title 10 of the *Code of Federal Regulations* (10 CFR) for the protection of the public and environment. The NRC does not collect or retain data on the forms and the forms are not sent to or received by the NRC. NRC Form 541/541A and NRC Form 542/542A are (1) mailed or electronically transferred to the intended consignee prior to the shipment arriving at the consignee or (2) delivered with the waste to the consignee. NRC Form 540 and 540A are required to be with the shipment regardless of which of the above methods is chosen.

6. *Who will be required or asked to respond:* NRC Form 540 and continuation Form 540A are completed by generators, collectors, and processors of LLW intended for ultimate disposal at a licensed land disposal facility.

7. *The estimated number of annual responses:* 4,616.

8. *The estimated number of annual respondents:* 712.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 3,462.

10. *Abstract:* The completed NRC Form 540 contains information needed to satisfy the Department of Transportation shipping paper requirements in 49 CFR part 172 and the waste manifesting requirements of the NRC's 10 CFR part 20. NUREG/BR–0204, Rev. 3, contains instructions for completing NRC Forms 540, 540A, 541, 541A, 542, and 542A. The forms were originally developed by the NRC at the request of low-level waste industry groups. The forms are intended to provide uniformity and efficiency in the collection of information contained in manifests which are required to control transfers of LLW intended for disposal at a land disposal facility. However, as stated in 10 CFR part 20, appendix G, ''Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information . . .''

The NRC previously noticed the availability of revisions to the Uniform Low-Level Radioactive Waste Manifest Forms in the **Federal Register** on June 25, 2021 (86 FR 33783). The information collection contained in the current extension request does not include any material changes to the forms, except for: (1) changes to the Paperwork Reduction Act statement to indicate that licensees may use equivalent forms, and (2) the deletion of the expiration date.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.

2. Is the estimate of the number of annual responses, the number of annual respondents, and the burden of the information collection accurate? Please explain your answer.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: August 5, 2022.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2022–17169 Filed 8–9–22; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service

Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 1, 2022, it filed with the Postal Regulatory Commission a *USPS Request To Add Priority Mail Contract 753 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–93, CP2022–97.

Sarah Sullivan,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2022–17172 Filed 8–9–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 5, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 754 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2022–94, CP2022–98.

Sarah Sullivan,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2022–17173 Filed 8–9–22; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95419; File No. SR–PEARL–2022–30]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX PEARL Options Fee Schedule To Remove Certain Credits and Increase Trading Permit Fees

August 4, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on July 26, 2022, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Pearl Options Fee Schedule (the ''Fee Schedule'') to amend its monthly Trading Permit [3] fees for Members [4] and no longer provide two monthly credits associated with Trading Permit and non-transaction fees.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange commenced operations in February 2017 [5] and adopted its initial fee schedule that waived fees for Trading Permits to trade on the Exchange.[6] Although the fee was waived, an initial fee structure was put in place in communicate our intent to charge a fee in the future. As a new exchange entrant, the Exchange chose to offer Trading Permits free of charge to encourage market participants to trade on the Exchange and experience, among things, the quality of the Exchange's technology and trading functionality. This practice is not uncommon. Newly-opened exchanges often do not charge fees or charge lower fees for certain services such as memberships to attract order flow to an exchange, and later amend their fees to reflect the true value of those services, absorbing all costs to provide those services in the meantime. Allowing new exchange entrants time to build and sustain market share through various pricing incentives before increasing non-transaction fees encourages market entry and promotes competition. It also enables these new exchanges to mature their markets and allow market participants to trade on the new exchanges without fees serving as a potential barrier to attracting memberships and order flow.[7]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Trading Permit'' means a permit issued by the Exchange that confers the ability to transact on the Exchange. *See* Exchange Rule 100.

[4] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of Exchange Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100 and the Definitions Section of the Fee Schedule.

[5] *See* MIAX PEARL Successfully Launches Trading Operations, dated February 6, 2017, *available at https://www.miaxoptions.com/sites/default/files/alert-files/MIAX_Press_Release_02062017.pdf.*

[6] *See* Securities Exchange Act Release No. 80061 (February 17, 2017), 82 FR 11676 (February 24, 2017) (SR–PEARL–2017–10).

[7] *See* Securities Exchange Act Release No. 94894 (May 11, 2022), 87 FR 29987 (May 17, 2022) (SR–BOX–2022–17) (stating, ''[t]he Exchange established this lower (when compared to other options exchanges in the industry) Participant Fee in order to encourage market participants to become Participants of BOX. . .''). *See also* Securities Exchange Act Release No. 90076 (October 2, 2020), 85 FR 63620 (October 8, 2020) (SR–MEMX–2020–10) (''MEMX Membership Fee Proposal'') (proposing to adopt the initial fee schedule and stating that ''[u]nder the initial proposed Fee Schedule, the Exchange proposes to make clear that it does not charge any fees for membership, market data products, physical connectivity or application sessions.''). MEMX has seen its market share increase and recently proposed to adopt a membership fee and fees for connectivity. *See* Securities Exchange Act Release Nos. 93927

Later in 2018, as the Exchange's market share increased,[8] it adopted a nominal fee for Trading Permits along with a tiered-volume based fee credit, known as the Trading Permit Fee Credit, and a Monthly Volume Credit.[9] The Exchange has not amended its Trading Permit fees since the fees were first adopted in 2018. The Exchange established the Trading Permit Fee Credit to continue to attract order flow and increase membership by lowering the costs for Members that connect via the MEO Interface [10] and FIX Interface.[11]

The lower Trading Permit Fees, Trading Permit Fee Credit and Monthly Volume Credit have served their purpose of incentivizing market participants to trade on the Exchange as the Exchange's market share continues to grow and increase since the fee and credits were established.[12] Therefore, the Exchange now proposes to amend the monthly Trading Permit fees for Members and to no longer provide two monthly credits associated with Trading Permit and non-transaction fees. The proposed changes are designed to update the Exchange's Trading Permit fees to reflect their current value based on the Exchange's market share and ability to deliver value to its customers through improved liquidity, enhanced functionality, and resilient trading technology, rather than their value when MIAX Pearl was a new options exchange entrant seeking to establish itself in a highly competitive space over five years ago. The Exchange reviewed similar fees charged by other options exchanges when considering the proposed fee levels as well as the impact on current Members and whether the proposed fee levels would continue to enable the Exchange to attract new Members and retain existing Members. The Exchange notes that it also socialized the proposed fee increases with current Members prior to first implementing the changes. During this process, the Exchange decided on price levels that it believes would aid and improve its competitive footing and some Members informed the Exchange that they anticipated a potential increase due to the lower rates the Exchange historically charged and the resiliency and performance of its trading platform. Each of these changes are described below.

Background

A Trading Permit confers the right to transact on the Exchange [13] and are available to all Members. The Exchange notes that requiring a Trading Permit to trade on the Exchange and charging a monthly fee for such is comparable to other monthly membership requirements and associated fees charged by other exchanges and is described further below. Trading Permits, like membership fees, grant access and allow Members to be active on the Exchange, thus providing the ability to submit orders and trade on the Exchange, in the manner consistent with the membership type. Without a Trading Permit, or ''membership'' as referred to by other exchanges, a Member cannot directly trade on the Exchange. Therefore, a Trading Permit is a means to directly access the Exchange, which offers meaningful value. The Exchange has not amended its Trading Permit fees since the fees were first adopted in 2018.[14]

Removal of Monthly Trading Permit Fee Credits

Monthly Volume Credit

The Exchange proposes to amend the Definitions section of the Fee Schedule to delete the definition and remove the credits applicable to the Monthly Volume Credit for Members. The Exchange established the Monthly Volume Credit in 2018 [15] to encourage Members to send increased Priority Customer [16] order flow to the Exchange, which the Exchange applied as a metric to the assessment of non-transaction fees for that Member. Prior to and during periods when this proposal was not in effect, the Exchange applied a different Monthly Volume Credit depending on whether the Member connects to the Exchange via the FIX or MEO Interface. Prior to and during periods when this proposal was not in effect, the Exchange assessed the Monthly Volume Credit to each Member that has executed Priority Customer volume along with that of its affiliates,[17] not including Excluded Contracts,[18] of at least 0.30% of MIAX Pearl-listed Total Consolidated Volume (''TCV''),[19] as set forth in the following table:

(January 7, 2022), 87 FR 2191 (January 13, 2022) (SR–MEMX–2021–19) (proposing to adopt membership fees); *and* 95299 (July 15, 2022), 87 FR 43563 (July 21, 2022) (SR–MEMX–2022–17) (proposing to adopt fees for connectivity). *See also, e.g.,* Securities Exchange Act Release No. 88211 (February 14, 2020), 85 FR 9847 (February 20, 2020) (SR–NYSENAT–2020–05), *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-national/rulefilings/filings/2020/SR-NYSENat-2020-05.pdf* (initiating market data fees for the NYSE National exchange after initially setting such fees at zero).

[8] The Exchange experienced a monthly average trading volume of 3.94% for the month of March 2018. *See* Market at a Glance, *available at www.miaxoptions.com* (last visited (June 22, 2022).

[9] *See* Securities Exchange Act Release No. 82867 (March 13, 2018), 83 FR 12044 (March 19, 2018) (SR–PEARL–2018–07).

[10] ''MEO Interface'' or ''MEO'' means a binary order interface for certain order types as set forth in Rule 516 into the MIAX Pearl System. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[11] ''FIX Interface'' means the Financial Information Exchange interface for certain order types as set forth in Exchange Rule 516. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[12] The Exchange experienced a monthly average trading volume of 4.92% for the month of June 2022. *See* Market at a Glance, *supra* note 8.

[13] *See* Exchange Rule 200(a).

[14] *See supra* note 9.

[15] *See* Market at a Glance, *supra* note 8.

[16] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial accounts(s). The number of orders shall be counted in accordance with Interpretation and Policy .01 of Exchange Rule 100. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100, including Interpretation and Policy .01.

[17] ''Affiliate'' means (i) an affiliate of a Member of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, or (ii) the Appointed Market Maker of an Appointed EEM (or, conversely, the Appointed EEM of an Appointed Market Maker). An ''Appointed Market Maker'' is a MIAX Pearl Market Maker (who does not otherwise have a corporate affiliation based upon common ownership with an EEM) that has been appointed by an EEM and an ''Appointed EEM'' is an EEM (who does not otherwise have a corporate affiliation based upon common ownership with a MIAX Pearl Market Maker) that has been appointed by a MIAX Pearl Market Maker, pursuant to the following process. A MIAX Pearl Market Maker appoints an EEM and an EEM appoints a MIAX Pearl Market Maker, for the purposes of the Fee Schedule, by each completing and sending an executed Volume Aggregation Request Form by email to *membership@miaxoptions.com* no later than 2 business days prior to the first business day of the month in which the designation is to become effective. Transmittal of a validly completed and executed form to the Exchange along with the Exchange's acknowledgement of the effective designation to each of the Market Maker and EEM will be viewed as acceptance of the appointment. The Exchange will only recognize one designation per Member. A Member may make a designation not more than once every 12 months (from the date of its most recent designation), which designation shall remain in effect unless or until the Exchange receives written notice submitted 2 business days prior to the first business day of the month from either Member indicating that the appointment has been terminated. Designations will become operative on the first business day of the effective month and may not be terminated prior to the end of the month. Execution data and reports will be provided to both parties. *See* the Definitions Section of the Fee Schedule.

[18] ''Excluded Contracts'' means any contracts routed to an away market for execution. *See* the Definitions Section of the Fee Schedule.

[19] ''TCV'' means total consolidated volume calculated as the total national volume in those classes listed on MIAX Pearl for the month for which the fees apply, excluding consolidated volume executed during the period of time in which the Exchange experiences an Exchange System Disruption (solely in the option classes of the affected Matching Engine). *See* the Definitions Section of the Fee Schedule.

Type of member connection	Monthly volume credit
Member that connects via the FIX Interface	$250
Member that connects via the MEO Interface	1,000

If a Member connects via both the MEO Interface and FIX Interface and qualifies for the Monthly Volume Credit based upon its Priority Customer volume, the greater Monthly Volume Credit shall apply to such Member. Prior to and during periods when this proposal was not in effect, the Monthly Volume Credit was a single, once-per-month credit towards the aggregate monthly total of non-transaction fees assessable to a Member.

The Exchange proposes an amendment to the Definitions section of the Fee Schedule to delete the definition and remove the Monthly Volume Credit. The Exchange established the Monthly Volume Credit when it first launched operations to encourage members to increase their order flow by providing a credit to those that exceeded a volume threshold. The Exchange believes that the Exchange's existing Priority Customer rebates and fees will continue to allow the Exchange to remain highly competitive and continue to attract order flow and maintain market share even without the Monthly Volume Credit.

Trading Permit Fee Credit

The Exchange proposes to amend Section (3)(b) of the Fee Schedule to remove the Trading Permit fee credit that is denoted in footnote ''*'' below the Trading Permit fee table. Prior to and during periods when this proposal was not in effect, the Trading Permit fee credit was applicable to Members that connected via both the MEO and FIX Interfaces. Members who connect via both the MEO and FIX Interfaces are assessed the rates for both types of Trading Permits, but these Members received a $100 monthly credit towards the Trading Permit fees applicable to the MEO Interface prior to and during periods when this proposal was not in effect. The Exchange proposes to remove the Trading Permit fee credit and delete footnote ''*'' from Section (3)(b) of the Fee Schedule.

The Exchange established the Trading Permit fee credit when it first launched operations to attract order flow and increase membership by lowering the costs for Members that connect via the MEO Interface and FIX Interface. The Trading Permit fee credit has achieved its purpose and the Exchange now believes that it is appropriate to remove this credit in light of the current operating conditions and membership population on the Exchange.

Amendments to Monthly Trading Permit Fees

The Exchange proposes to amend the Fee Schedule to amend the fees for Trading Permits. As a self-regulatory organization, the Exchange's membership department reviews applicants to ensure that each application complies with Exchange Rule 200 as well as other requirements for membership.[20] Applicants must meet the Exchange's qualification criteria prior to approval. The new member review includes, but is not limited to, the registration and qualification of associated persons, financial health of the proposed member, the validity of the required clearing relationship, and the history of disciplinary matters. Approved new Members are required to comply with Exchange's By-Laws and Rules and are subject to regulation by the Exchange. The Exchange also has ongoing regulatory responsibilities over its Members.

The Exchange believes that there are many factors that may cause a market participant to decide to become a member of a particular exchange. Among various factors, the Exchange believes market participants consider: (i) an exchange's available liquidity in options series; (ii) trading functionality, latency, reliability, throughout, access to liquidity, and determinism offered on a particular market; (iii) product offerings; (iv) customer service on an exchange; and (v) transactional pricing. The Exchange believes that the decision to become a member of an exchange, particularly as a registered market maker, is a complex one that is not solely based on non-transactional costs assessed by an exchange. Market participants weigh the tradeoff between where they choose to deploy liquidity versus where trading opportunities exist. Of course, the cost of membership may factor into a decision to become a member of a certain exchange, but the Exchange believes it is by no means the only factor when comparing exchanges.

The Exchange assesses Trading Permit fees based upon the monthly total volume executed by the Member and its Affiliates on the Exchange across all origin types, not including Excluded Contracts, as compared to the total TCV in all MIAX Pearl-listed options. The Exchange adopted a tier-based fee structure based upon the volume-based tiers detailed in the definition of ''Non-Transaction Fees Volume-Based Tiers'' [21] in the Definitions section of the Fee Schedule. The Exchange also assesses Trading Permit fees based upon the type of interface used by the Member to connect to the Exchange—the FIX Interface and/or the MEO Interface.

The Exchange has two types of Members, Electronic Exchange Members [22] (''EEMs'') and Market Makers.[23] The Exchange currently charges monthly fees for Trading Permits pursuant to Exchange Rule 200(f), which varies based on the interface used by the Member and the Member's monthly trading volumes. The Exchange provides two interfaces to access the MIAX Pearl System,[24] the FIX Interface and MEO Interface, and all Members are able to use either interface based on their business models and needs. The FIX Interface is the industry-wide uniform message format and provides lower bandwidth, less capacity, and fewer Exchange resources. EEMs, who are primarily order flow providers, are the only users of the FIX Interface.[25] No Market Maker uses the FIX Interface. Meanwhile, the MEO Interface is the more robust interface offering lower latency and higher throughput. Market Makers only use the MEO Interface.

Today, seven (7) Members that are registered solely as EEMs elect to utilize the MEO Interface. Based on their own business decisions and needs, some EEMs may elect to utilize the MEO Interface today due to its lower latency

[20] The Exchange's Membership Department must ensure, among other things, that an applicant is not statutorily disqualified.

[21] *See* the Definitions Section of the Fee Schedule for the monthly volume thresholds associated with each Tier.

[22] The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[23] The term ''Market Maker'' or ''MM'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of the Exchange Rules. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[24] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[25] The Exchange does not propose to amend the fees for EEM Clearing Firms, which is set at $250 per month and not based on the amount of volume conducted on the Exchange. The term ''EEM Clearing Firm'' means an EEM that solely clears transactions on the Exchange and does not connect to the Exchange via either the FIX Interface or MEO Interface. *See* the Definitions Section of the Fee Schedule.

and higher throughput. Also, six (6) Members are registered as both an EEM and Market Maker. These Members may choose to utilize only the MEO Interface for acting as either EEM or Market Maker, not only based on their own business needs, but also as a means to streamline and simplify their architecture between them and the Exchange. Each of these Members are able to utilize the FIX Interface for their EEM activities and avail themselves to the lower rates if they believe the FIX Interface is aligned with their business needs.

Market Makers only use the MEO Interface because it provides functionality that is designed to assist Market Makers in satisfying their market making obligations. The Exchange offers three time-in-force modifiers: [26] Day Limit (''Day''), Immediate-Or-Cancel (''IOC''), and Good 'Til Cancelled (''GTC'').[27] While all order types are available for use on either interface, only the time-in-force modifiers of IOC and Day are available on the MEO Interface.[28] Market Makers utilize the time-in-force of Day on orders to be posted on the MIAX Pearl Options Book [29] and to meet Market Makers' continuous quoting obligations under Exchange Rule 605(d).[30] Other Market Makers that primarily remove liquidity tend to be more latency sensitive and utilize the time-in-force of IOC on orders when looking to remove liquidity from the MIAX Pearl Options Book. The MEO Interface allows the submission of Cancel-Replacement orders,[31] which allow for the immediate cancellation of a previously received order and the replacement of that order with a new order with new terms and conditions.[32] Cancel-Replacement orders are primarily used by Market Makers as part of their continuous quoting obligations. Market Makers only use the MEO Interface due to its lower latency, higher throughput, available time-in-force instructions and order types that assist them in satisfying their market making obligations. Market Makers do not use the FIX Interface due to the unavailability of the above functionality. While EEMs primarily use the FIX Interface, certain EEMs chose to use the MEO interface due to its enhanced functionality and based on their own business models.

Current Trading Permit Fees. Prior to and during periods when this proposal was not in effect, each Member who connected to the System via the FIX Interface was assessed the following monthly Trading Permit fees:

(i) if its volume falls within the parameters of Tier 1 of the Non-Transaction Fees Volume-Based Tiers, or volume up to 0.30%, $250;

(ii) if its volume falls within the parameters of Tier 2 of the Non-Transaction Fees Volume-Based Tiers, or volume above 0.30% up to 0.60%, $350; and

(iii) if its volume falls within the parameters of Tier 3 of the Non-Transaction Fees Volume-Based Tiers, or volume above 0.60%, $450.

Each Member who connected to the System via the MEO Interface was assessed the following monthly Trading Permit fees:

(i) if its volume falls within the parameters of Tier 1 of the Non-Transaction Fees Volume-Based Tiers, or volume up to 0.30%, $300;

(ii) if its volume falls within the parameters of Tier 2 of the Non-Transaction Fees Volume-Based Tiers, or volume above 0.30% up to 0.60%, $400; and

(iii) if its volume falls within the parameters of Tier 3 of the Non-Transaction Fees Volume-Based Tiers, or volume above 0.60%, $500.

Proposed Trading Permit Fees. The pull on Exchange resources associated with providing ongoing Member support, onboarding/off boarding technology requests, monitoring, reporting, and the surveillance and retention of increased message traffic due to increased trading volumes continue to increase since Trading Permit fees were first adopted in 2018.[33] The Exchange proposes to amend its Trading Permit fees as follows. Each Member who connects to the System via the FIX Interface will be assessed the following monthly Trading Permit fees:

(i) if its volume falls within the parameters of Tier 1 of the Non-Transaction Fees Volume-Based Tiers, $500;

(ii) if its volume falls within the parameters of Tier 2 of the Non-Transaction Fees Volume-Based Tiers, $1,000; and

(iii) if its volume falls within the parameters of Tier 3 of the Non-Transaction Fees Volume-Based Tiers, $1,500.

Each Member who connects to the System via the MEO Interface will be assessed the following monthly Trading Permit fees:

(i) if its volume falls within the parameters of Tier 1 of the Non-Transaction Fees Volume-Based Tiers, $2,500;

(ii) if its volume falls within the parameters of Tier 2 of the Non-Transaction Fees Volume-Based Tiers, $4,000; and

(iii) if its volume falls within the parameters of Tier 3 of the Non-Transaction Fees Volume-Based Tiers, $6,000.

As discussed above, both the MEO Interface and FIX Interface are available to all Members and each Member may choose which interface to utilize based on their own business needs. The MEO Interface is primarily used by Market Makers due to its robustness, lower latency, and higher throughput [34] and, as discussed below, utilizes greater Exchange resources due to the increased volume of message traffic that travels through the MEO interface. Trading Permit fees for Members who connect through the MEO Interface are, therefore, higher than the Trading Permit fees for Members who connect through the FIX Interface. The FIX Interface provides lower capacity and bandwidth and, therefore, utilizes less Exchange resources. The FIX Interface is primarily used by order flow providers who tend to be less latency sensitive and submit less orders and messages than Market Makers.

The Exchange has not amended its Trading Permit fees since the fees were first adopted in 2018.[35] The Exchange notes that its affiliates, Miami International Securities Exchange, LLC (''MIAX'') and MIAX Emerald, LLC (''MIAX Emerald''), charge EEMs a similar, fixed flat trading permit fee of

[26] *See* MIAX Pearl Options Exchange User Manual, Section 6, Order Types, *available at https://www.miaxoptions.com/exchange-functionality/pearl* (last visited June 30, 2022).

[27] *See, e.g.,* Exchange Rule 516.

[28] *See* preamble to Exchange Rule 516 (noting that not all order types and modifiers are available for use on each of the MEO Interface and the FIX Interface). *See also* Section 4.1.1.2 of the MEO Interface Specification, *available at https://www.miaxoptions.com/sites/default/files/page-files/MIAX_Express_Orders_MEO_v2.0.pdf* (indicating that the time-in-force instructions of IOC and Day are available on the MEO interface).

[29] The term ''Book'' means the electronic book of buy and sell orders and quotes maintained by the System. *See* Exchange Rule 100.

[30] Only the time-in-force modifiers of IOC and Day are available on the MEO Interface. *See* Exchange Rule 516 (noting that not all order types and modifiers are available for use on each of the MEO Interface and the FIX Interface). *See also* MIAX Pearl Options Exchange MEO Interface Specification, Section 4.1.1.2, *available at https://www.miaxoptions.com/sites/default/files/page-files/MIAX_Express_Orders_MEO_v2.0.pdf* (indicating that the time-in-force instructions of IOC and Day are available on the MEO interface).

[31] *See* MIAX Pearl Options Exchange User Manual, Section 6, Interfaces and Liquidity Types, *available at https://www.miaxoptions.com/exchange-functionality/pearl* (last visited May 16, 2022).

[32] *See* Exchange Rule 516(d).

[33] *See supra* note 9.

[34] Certain EEMs also choose to use the MEO interface due to its enhanced functionality and based on their own business models.

[35] *Id.*

$1,500,[36] which equals the top tier proposed herein for users of the FIX Interface and also entirely consists of EEMs. MIAX and MIAX Emerald also charge tiered trading permit fees to Market Makers as the Exchange proposes herein for users of the MEO Interface, which also primarily consists of Market Makers. However, the Exchange's proposed fees for users of the MEO Interface range from $2,500 to $6,000 while the fees on MIAX and MIAX Emerald range from $7,000 to $22,000. The Exchange also proposes to base its pricing on trading volume while MIAX and MIAX Emerald base their trading permit fees on number of options classes assigned to the Market Maker or the percentage of volume in option classes.[37] This is due to the difference in options assignments between the Exchange, and MIAX and MIAX Emerald. On MIAX and MIAX Emerald, Market Makers are assigned by options class, and are required to quote nearly all options in the class. On the Exchange, Market Makers are assigned by series, not class, and, therefore, trading volume is the more equitable and metric by which to gauge their use of the Exchange systems and related Trading Permit Fee.

As illustrated by the table below, the Exchange notes that the proposed fees for the Exchange's Trading Permits are in line with, or cheaper than, the similar trading permit and membership fees charged by other options exchanges. The below table also illustrates how the Exchange has historically undercharged for membership via Trading Permits as compared to other options exchanges. The Exchange believes other exchanges' membership and trading permit fees are useful examples of alternative approaches to providing and charging for membership and provides the below table for comparison purposes only to show how the Exchange's proposed fees compare to fees currently charged by other options exchanges for similar membership.

Exchange	Monthly membership/trading permit fee
MIAX Pearl Options (as proposed)	Trading Permit access via FIX Interface: Tier 1: $500. Tier 2: $1,000. Tier 3: $1,500. Trading Permit access via MEO Interface: Tier 1: $2,500. Tier 2: $4,000. Tier 3: $6,000.
BOX Options Exchange LLC ("BOX") [38].	Participant Fee: $1,500. Electronic Market Maker Trading Permit Fees: Tier 1 (up to and including 10 classes): $4,000. Tier 2 (up to and including 40 classes): $6,000. Tier 3 (up to and including 100 classes): $8,000. Tier 1 (over 100 classes): $10,000.
NYSE Arca, Inc. ("NYSE Arca") [39]	Options Trading Permits: Office and Clearing Firms: $1,000. Market Makers: 1st OTP—$8,000 for up to 60 plus the bottom 45% of option issues. 2nd OTP—Additional $6,000 for up to 150 plus the bottom 45% of option issues. 3rd OTP—Additional $5,000 for up to 500 plus the bottom 45% of option issues. 4th OTP—Additional $4,000 for up to 1,100 plus the bottom 45% of option issues. 5th OTP—Additional $3,000 for all option issues. 6th–9th OTP—Additional $2,000. 10th or more OTPs—$500 for all options issues.
NYSE American, LLC ("NYSE American") [40].	ATP Trading Permits: Clearing Member: $1,000. Order Flow Provider: $1,000. Market Makers: $8,000 for up to 60 plus the bottom 45% of option issues. Additional $6,000 for up to 150 plus the bottom 45% of option issues. Additional $5,000 for up to 500 plus the bottom 45% of option issues. Additional $4,000 for up to 1,100 plus the bottom 45% of option issues. Additional $3,000 for all option issues. Additional $2,000 for 6th to 9th ATPs (plus additional fee for premium products).
Nasdaq PHLX LLC ("Nasdaq PHLX") [41].	Streaming Quote Trader ("SQT") permit fees: Tier 1 (up to 200 option classes): $0.00. Tier 2 (up to 400 option classes): $2,200. Tier 3 (up to 600 option classes): $3,200. Tier 4 (up to 800 option classes): $4,200. Tier 5 (up to 1,000 option classes): $5,200. Tier 6 (up to 1,200 option classes): $6,200. Tier 7 (all option classes): $7,200. Remote Market Maker Organization ("RMMO") permit fees: Tier 1 (less than 100 option classes): $5,000. Tier 2 (more than 100 and less than 999 option classes): $8,000. Tier 3 (1,000 or more option classes): $11,000.
Nasdaq ISE LLC ("Nasdaq ISE") [42]	Access Fees:

[36] *See* the MIAX Fee Schedule, Section 3)b) and MIAX Emerald Fee Schedule, Section 3)b), *available at https://www.miaxoptions.com/fees* (last visited June 30, 2022).

[37] Both MIAX and MIAX Emerald charge Market Makers a monthly fee of $7,000 for up to 10 classes or up to 20% of classes assigned by volume, $12,000 for up to 40 classes or up to 35% of classes assigned by volume, $17,000 for up to 100 classes or up to 50% of classes assigned by volume, or $22,000 for over 100 classes or over 50% of classes assigned by volume up to all classes listed on MIAX or MIAX Emerald, as applicable. *Id.*

Exchange	Monthly membership/trading permit fee
Cboe Exchange, Inc. ("Cboe") [43] ...	Electronic Access Members ("EAMs"): $500. Primary Market Maker: $5,000 per membership. Competitive Market Maker: $2,500 per membership. Electronic Trading Permit Fees: Market Maker: $5,000. Electronic Access Permit: $3,000. Clearing TPH Permit: $2,000.
Cboe C2 Exchange, Inc. ("Cboe C2") [44].	Access Permit Fees for Market Makers: $5,000. Electronic Access Permits: $1,000.
Cboe BZX Exchange, Inc. ("Cboe BZX Optis") [45].	$500 where member has an ADV < 5,000 contracts traded. [46] $1,000 where member has an ADV ≥ 5,000 contracts traded.

Implementation and Procedural History

The proposed rule change will be immediately effective. The Exchange initially filed this proposal on July 1, 2021, with the proposed fees being immediately effective.[47] Between August 2021 and February 2022, the Exchange withdrew and refiled the proposed rule change, each time to meaningfully attempt to provide additional justification for the proposed fee changes, provide enhanced details regarding the Exchange's cost methodology, and address questions contained in the Commission's suspension orders.[48] The Commission received one comment letter on the filings.[49] The Commission again suspended the proposed fees on February 18, 2022.[50] The Commission received one comment letter on that filing.[51] The Exchange then provided Trading Permits at the lower rates for the month of March 2022 and absorbed all associated costs with the lower rates.

On March 30, 2022, the Exchange withdrew the proposed rule change that was previously suspended by the Commission on February 18, 2022. After providing Trading Permits at the lower rates for the month of March 2022, on March 30, 2022, the Exchange submitted a revised proposal for effectiveness beginning April 1, 2022.[52] This revised proposal argued that the proposed fees were constrained by competition based on a similar filing for permit/membership fees by MEMX LLC ("MEMX").[53] The Commission received one comment letter on that filing.[54] The Exchange withdrew this revised proposal and submitted a further revised filing providing additional support for its competition based

[38] *See* BOX fee schedule, Section 1, *available at https://boxexchange.com/assets/BOX-Fee-Schedule-as-of-June-1-2022-1.pdf* (last visited June 29, 2022). BOX's Participant Fee is the analog to the Exchange's Trading Permit fee for Members who use the FIX interface. BOX's Electronic Market Maker Trading Permit fee is the analog for the Exchange's Trading Permit fee for Members who use the MEO interface. BOX had an average daily market share of 6.26% as of June 30, 2022. *See* Market at a Glance, *supra* note 8.

[39] *See* NYSE Arca Options Fees and Charges, OTP Trading Participant Rights, p.1, *available at https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf* (last visited July 12, 2022). NYSE Arca recently increased this Options Trading Permit Fees approximately 45%. *See* Securities Exchange Act Release No. 95142 (June 23, 2022), 87 FR 38786 (June 29, 2022) (SR–NYSEArca–2022–36). Under the new fee structure, it effectively costs a Market Maker $26,000 per month to trade all options issues on NYSE Arca. NYSE Arca's Options Trading Permit fee is the analog to the Exchange's Trading Permit fee for Members who use the FIX interface. NYSE Arca's Options Trading Permit fee for Market Makers is the analog for the Exchange's Trading Permit fee for Members who use the MEO interface.

[40] *See* NYSE American Options Fee Schedule, Section III, Monthly Trading Permit, Rights, Floor Access and Premium Product Fees, p. 23–24, *available at https://www.nyse.com/publicdocs/nyse/markets/american-options/NYSE_American_Options_Fee_Schedule.pdf* (last visited May 16, 2022). Under this fee structure, it effectively costs a Market Maker $26,000 per month to trade all options issues on NYSE American. NYSE American's ATP Trading Permit fee for Clearing Members and Order Flow Providers is the analog for the Exchange's Trading Permit fee for Members that use the FIX interface. NYSE American's ATP Trading Permit fee for Market Makers is the analog for the Exchange's Trading Permit fee for Members that use the MEO interface.

[41] *See* Nasdaq PHLX Options 7 Pricing Schedule, Section 8. Membership Fees, *available at https://listingcenter.nasdaq.com/rulebook/phlx/rules/Phlx%20Options%207* (last visited May 16, 2022). Nasdaq PHLX Options' SQT and RMMO fees is the analog to the Exchange's Trading Permit fee for Members that use the MEO Interface.

[42] *See* Nasdaq ISE Options 7 Pricing Schedule, Section 8.A. Access Services, *available at https://listingcenter.nasdaq.com/rulebook/ise/rules/ISE%20Options%207* (last visited May 16, 2022). Nasdaq ISE Options' EAM Access Fee is the analog to the Exchange's Trading Permit fee for Members that use the FIX Interface. Nasdaq ISE Options' Primary and Competitive Market Maker Access Fees are the analog to the Exchange's Trading Permit fee for Members that use the MEO Interface.

[43] *See* Cboe Fee Schedule, Electronic Trading Permit Fees, *available at https://cdn.cboe.com/resources/membership/Cboe_FeeSchedule.pdf* (last visited June 30, 2022). Cboe's Electronic Access Permit fee and Clearing TPH fee are the analog to the Exchange's Trading Permit fee for Members that use the FIX Interface. Cboe's Market Maker Permit fee is the analog to the Exchange's Trading Permit fee for Members that use the MEO Interface.

[44] *See* Cboe C2 Fee Schedule, Access Fees, *available at https://www.cboe.com/us/options/membership/fee_schedule/ctwo/* (last visited June 30, 2022). C2's Market Maker Access Permit fee is the analog to the Exchange's Trading Permit fee for Members that use the MEO Interface. C2's Electronic Access Permit fee is the analog to the Exchange's Trading Permit fee for Members that use the FIX Interface.

[45] *See* ''Membership Fees'' section of the Cboe BZX Options Fee Schedule, *available at https://www.cboe.com/us/options/membership/fee_schedule/bzx* (last visited June 30, 2022). The Exchange understands Cboe BZX Options charges the same Membership Fee to all of its Options Members.

[46] Under the Exchange's tiered structure, a Member may trade approximately 106,000 more contracts on the Exchange than on Cboe BZX Options and continue to qualify for the Exchange's lowest tier. For example, a Member would qualify for Tier 1 of the Exchange's tiered pricing structure where that Member's total volume as a percentage of TCV is between 0.00% and 0.30%. Assuming an average of 37 million contracts are traded each day during a month, that Member would qualify for Tier 1 where that Member traded less than 111,000 contracts that day and be charged $500, the same fee as Cboe BZX Options, where that Member connects via the FIX Interface. On Cboe BZX Options, the Exchange understands that same member would no longer qualify for their lowest tier when their ADV equals or exceeds 5,000 contracts and be charged a fee of $1,000 for that month.

[47] *See* Securities Exchange Act Release No. 92366 (July 9, 2021), 86 FR 37379 (SR–PEARL–2021–32).

[48] *See* Securities Exchange Act Release Nos. 92797 (August 27, 2021), 86 FR 49399 (September 2, 2021) (SR–PEARL–2021–32) (''Suspension Order 1''); 93555 (November 10, 2021), 86 FR 64254 (November 17, 2021) (SR–PEARL–2021–54); 93895 (January 4, 2022), 87 FR 1217 (January 10, 2022) (SR–PEARL–2021–59).

[49] *See* Letter from Richard J. McDonald, Susquehanna International Group, LLC (''SIG''), to Vanessa Countryman, Secretary, Commission, dated September 28, 2021 (''SIG Letter 1'').

[50] *See* Securities Exchange Act Release No. 94287 (February 18, 2022), 87 FR 10837 (February 25, 2022) (SR–PEARL–2022–05) (''Suspension Order 2'').

[51] *See* Letter from Richard J. McDonald, SIG, to Vanessa Countryman, Secretary, Commission, dated March 15, 2022 (''SIG Letter 2'').

[52] *See* Securities Exchange Act Release No. 94696 (April 12, 2022), 87 FR 22987 (April 18, 2022) (SR–PEARL–2022–09).

[53] *See* Securities Exchange Act Release No. 93927 (January 7, 2022), 87 FR 2191 (January 13, 2022) (SR–MEMX–2021–19) (proposal to adopt monthly membership fees).

[54] *See* Letter from Brian Sopinsky, SIG, to Vanessa Countryman, Secretary, Commission, dated May 9, 2022 (''SIG Letter 3'').

justification on May 17, 2022.[55] In response to feedback from Commission Staff, the Exchange then withdrew that revised proposal and submitted a further revised proposal to provide additional support for the proposed fee change and to enhance its competition based justification on July 12, 2022.[56] Again, in response to feedback from Commission Staff, the Exchange withdrew that revised proposal and submitted this further revised proposal to provide additional support for the proposed fee change and to enhance its competition based justification on July 26, 2022.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[57] in general, and furthers the objectives of Section 6(b)(4) of the Act[58] in particular, in that it is an equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The proposed changes to the Fee Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for order flow, which constrains its pricing determinations. The fact that the market for order flow is competitive has long been recognized by the courts. *In NetCoalition* v. *Securities and Exchange Commission*, the D.C. Circuit stated, ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . .'' [59]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention to determine prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [60]

Congress directed the Commission to ''rely 'on competition, whenever possible, in meeting its regulatory responsibilities for overseeing the SROs and the national market system.' '' [61] As a result, the Commission has historically relied on competitive forces to determine whether a fee proposal is equitable, fair, reasonable, and not unreasonably or unfairly discriminatory. ''If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.'' [62] Accordingly, ''the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.'' [63]

In its 2019 guidance on fee proposals, Commission staff indicated that they would look at factors beyond the competitive environment, such as cost, only if a ''proposal lacks persuasive evidence that the proposed fee is constrained by significant competitive forces.'' [64] The Commission staff further indicated in its 2019 guidance that an exchange can demonstrate competitive forces exist by showing that ''substantially similar but not identical'' substitutable products or services exist and that ''elasticity of demand'' may be evidence that competitive forces exist.[65]

The Exchange believes that there are many factors that may cause a market participant to decide to become a member of a particular exchange including: (i) an exchange's available liquidity in options series; (ii) trading functionality offered on a particular market; (iii) product offerings; (iv) customer service on an exchange; and (v) transactional pricing. As discussed above, the Exchange believes that the decision to become a member of an exchange, particularly as a registered market maker, is a complex one that is not solely based on non-transactional costs assessed by an exchange. Market participants weigh the tradeoff between where they choose to deploy liquidity versus where trading opportunities exist. Of course, the cost of membership, ports and market data may factor into a decision to become a member of a certain exchange, but the Exchange believes it is by no means the only factor when comparing exchanges. In general, there are a number of factors that market participants may consider when deciding to become a member of the Exchange or any other options exchange.

Market Makers

Market makers play an important role on options exchanges as they provide liquidity. In options markets, registered market makers are assigned options series[66] and are required to quote in those options series for a specified time period during the day.[67] Typically, a lead or primary market maker[68] will be required to quote for a longer period of time during the day as compared to other market makers registered on an exchange.[69] Additionally, market makers are typically required to quote within a certain width on options markets.[70] Greater liquidity on options

[55] *See* Securities Exchange Act Release No. 94993 (May 26, 2022), 87 FR 33518 (June 2, 2022) (SR–PEARL–2022–23).

[56] *See* SR–PEARL–2022–28.

[57] 15 U.S.C. 78f(b).

[58] 15 U.S.C. 78f(b)(4) and (5).

[59] *See* NetCoalition, 615 F.3d at 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[60] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[61] *See* NetCoalition, 615 F.3d at 534–35; *see also* H.R. Rep. No. 94–229 at 92 (1975) (''[I]t is the intent of the conferees that the national market system evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed.'').

[62] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR–NYSEArca–2006–21).

[63] *Id.*

[64] *See* U.S. Securities and Exchange Commission, ''Staff Guidance on SRO Rule filings Relating to Fees,'' (May 21, 2019), *available at https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees.*

[65] *Id.*

[66] *See* Exchange Rule 602, Phlx, ISE, Nasdaq GEMX, Inc. (''GEMX''), Nasdaq MRX, Inc. (''MRX''), Nasdaq BX, Inc. (''BX'') and Nasdaq Options Market (''NOM'') Options 2, Section 3; Cboe Rule 5.50; BOX Exchange LLC (''BOX'') Rule 8030; MIAX Rule 602; and NYSE Arca Rule 6.35–O.

[67] *See* Exchange Rule 604, ISE, GEMX and MRX, Phlx, BX and NOM Options 2, Section 5; Cboe Rule 5.52; BOX Rule 8050; MIAX Rule 604; and NYSE Arca Rule 6.37A–O.

[68] Options markets refer to the primary market maker on an exchange in several ways.

[69] *See* Exchange Rule 604, BX Options 2, Section 4; ISE, GEMX and MRX, and Phlx Options 2, Section 5; BOX Rule 8055; MIAX Rule 604; and NYSE Arca Rule 6.37A–O.

[70] *See* BX Options 2, Section 4; ISE, GEMX and MRX, Phlx and NOM Options 2, Section 5; and Cboe Rule 5.52; BOX Rule 8040.

markets benefits all market participants by providing more trading opportunities and attracting greater participation by market makers. An increase in the activity of market makers in turn facilitates tighter spreads. Market participants are attracted to options markets that have ample liquidity and tighter spreads in options series.

Trading Functionality

An exchange's trading functionality attracts market participants who may elect, for example, to submit an order into a price improving auction,[71] enter a complex order,[72] or utilize a particular order type.[73] Different options exchanges offer different trading functionality to their members. For example, with respect to priority and allocation of an order book, some options exchanges have price/time allocation,[74] some have a size pro-rata allocation,[75] while other exchanges offer both allocation models.[76] The allocation methodology on a particular options exchange's order book may attract certain market participants. Also, the manner in which some options markets structure their solicitation auction,[77] or opening process,[78] may be attractive to certain market participants. Finally, some exchanges have trading floors [79] which may accommodate trading for certain market participants or trading firms.[80]

Product Offerings

Introducing new and innovative products to the marketplace designed to meet customer demands may attract market participants to a particular options venue. New products in the options industry may allow market participants greater trading and hedging opportunities, as well as new avenues to manage risks. The listing of new options products enhances competition among market participants by providing investors with additional investment vehicles, as well as competitive alternatives, to existing investment products. An exchange's proprietary product offering may attract order flow to a particular exchange to trade a particular options product.[81]

Transaction Pricing

The pricing available on a particular exchange may impact a market participant's decision to submit order flow to a particular options venue. The options industry is competitive. Clear substitutes to the Exchange exist in the market for options security transaction services; the Exchange is only one of sixteen options exchanges to which market participants may direct their order flow and memberships. Within this environment, market participants can freely, and often do, shift their order flow and memberships among the Exchange and competing venues in response to changes in their respective pricing schedules.

* * * * *

The Exchange believes the fees in this case are reasonable and constrained by competitive forces. Evidence is set forth below showing that substitutable products and elasticity of demand exist when it comes to purchasing a Trading Permit or membership on an exchange.

Trading Permit Fee Increase

Trading Permit and Similar Membership Fees Are Constrained by Competition

The Exchange's Trading Permit Fees are subject to significant competitive forces as evidenced by available substitutes and elasticity of demand. As discussed above, the Exchange believes that there are many factors that may cause a market participant to decide to become a member of a particular exchange including: (i) an exchange's available liquidity in options series; (ii) trading functionality, latency, reliability, throughout, access to liquidity, and determinism offered on a particular market; (iii) product offerings; (iv) customer service on an exchange; and (v) transactional pricing. The Exchange believes that the decision to become a member of an exchange is a complex one that is not solely based on non-transactional costs assessed by an exchange.

The Exchange believes that there is value in being a Member of the Exchange and retaining that Membership as the Exchange's market share has grown. Exchanges compete with each other for memberships and must consider this competitive dynamic when setting fees for memberships, such as Trading Permits. In this case, the proposed Trading Permit fees are reasonable and constrained by competition because, as illustrated by the above table, they are in the range of similar types of membership fees charged to analogous categories of market participants by other exchanges, including those with similar market share.[82] The proposed monthly Trading Permit fees are also lower than or comparable to the membership and trading permit fees imposed by several other national securities exchanges that charge such fees.[83] Should the Exchange seek to adopt Trading Permit Fees that are higher than that of other exchanges, it would risk losing Members and having them potentially connect to the Exchange via other means. Becoming a member of the exchange does not ''lock'' a potential member into a market or diminish the overall competition for exchange services. The decision to become a member of an exchange is made at the beginning of the relationship, and is no less subject to competition than trading fees or market data.

Availability of Substitutes. The Commission staff indicated in its 2019 guidance that an exchange can demonstrate competitive forces exist by showing that ''substantially similar but not identical'' substitutable products or services exist.[84] That is clearly the case here. No broker-dealer is required to become a Member of the Exchange. Instead, many market participants waited for the Exchange to grow to a certain percentage of market share before they decided to become an Exchange Member. In addition, many market participants still have not joined the Exchange despite the Exchange's growth in recent years to consistently be

[71] *See* ISE, GEMX, MRX, Phlx and BX Options 3, Section 13; MIAX Rule 515A; Cboe Rule 5.37; and BOX Rules 7150 and 7245. The Exchange does not currently offer a price improving auction.

[72] *See* Phlx and ISE Options 3, Section 14; MIAX Rule 518; Cboe Rule 5.33; BOX Rule 7240; and NYSE Arca Rule 6.91–O. The Exchange does not currently offer complex order functionality.

[73] *See* Exchange Rule 516, ISE, GEMX, MRX, Phlx, BX and NOM Options 3, Section 7; MIAX Rule 516; Cboe Rule 5.6; BOX Rule 7110; and NYSE Arca Rule 6.62–O.

[74] *See* Exchange Rule 514, Cboe Rule 5.85; BOX Rule 7130; and NYSE Arca Rule 6.76–O.

[75] *See* Phlx, ISE, GEMX and MRX Options 3, Section 10; and BOX Rule 7135.

[76] *See* BX Options 3, Section 10. While BX's rule permits both price/time and size pro-rata allocation, all symbols on BX are currently designated as Price/Time. See also BOX Rules 7130 and 7135. MIAX's rule permits both Price-Time and Pro-Rata allocation. See also MIAX Rule 514.

[77] *See* ISE, GEMX and MRX Options 3, Section 11; NYSE American Rules 971.1NY and 971.2NY; and Cboe Rule 5.39.

[78] *See* Exchange Rule 503, ISE, GEMX, MRX, Phlx, BX and NOM Options 3, Section 8; Cboe Rule 5.31, MIAX Rule 503, BOX Rule 7070, and NYSE Arca Rule 6.64–O.

[79] Today, Phlx, Cboe, BOX, NYSE Arca, and NYSE American LLC have a trading floor. Trading floors require an on-floor presence to execute options transactions.

[80] There are certain features of open outcry trading that are difficult to replicate in an electronic trading environment. The Exchange has observed, and understands from various market participants, that they have had difficulty executing certain orders, such as larger orders and high-risk and complicated strategies, in an all-electronic trading configuration without the element of human interaction to negotiate pricing for these orders.

[81] *See, e.g.,* options on the Nasdaq-100 Index® available on ISE, GEMX and Phlx and Cboe's Market Volatility Index®. Currently, the Exchange does not list any proprietary products.

[82] *See supra* notes 38–46 and accompanying text.

[83] *See id.*

[84] *See supra* note 64.

approximately 4–5% of the overall equity options market share. To illustrate, the Exchange currently has 41 Members.[85] However, based on publicly available information regarding a sample of the Exchange's competitors, NYSE American Options has 75 members, NYSE Arca Options has 71 members, and Cboe has 94 members.[86] Accordingly, the vigorous competition among national securities exchanges provides many alternatives for firms to voluntarily decide whether membership to the Exchange is appropriate and worthwhile, and no broker-dealer is required to become a member of the Exchange. Specifically, neither the trade-through requirements under Regulation NMS nor broker-dealers' best execution obligations require a broker-dealer to become a member of every exchange.

The Exchange acknowledges that competitive forces may compel certain broker-dealers to be members of all equity options exchanges based on their business models. These broker-dealers may engage in latency sensitive trading strategies that benefit from being a member and connecting directly to an exchange based on the business model they choose to employ. Competitive forces that may drive certain broker-dealers to become members of each exchange based on their business models is not unique to the options market. This dynamic also exists in equities and acknowledged by MEMX and considered by the Commission in a recent MEMX proposal to adopt a monthly membership fee.[87] However, the Exchange believes that the proposed fees are reasonable, equitably allocated and not unfairly discriminatory, even for a broker-dealer that deems it necessary to join the Exchange for business purposes, as those business reasons should presumably result in revenue capable of covering the proposed fees, just as one may do when considering whether to become an member of an equity exchange.

Other broker-dealers may not find a need in becoming a member of all or some exchanges. There is no requirement, regulatory or otherwise, that any broker-dealer connect to and access any (or all of) the available options exchanges. One other exchange recently noted in a proposal to amend their own trading permit fees that of the 62 market making firms that are registered as Market Makers across Cboe, MIAX, and BOX, 42 firms access only one of the three exchanges.[88] Further, the Exchange and its affiliates, MIAX and MIAX Emerald, have a total of 47 members. Of those 47 total members, 35 are members of all three exchanges, four are members of only two (2) exchanges, and eight (8) are members of only one exchange. Of those that are Market Makers today on the Exchange, two (2) are not registered as Market Makers on MIAX and one (1) is not registered as a Market Maker on MIAX Emerald. Broken down even further, of those Market Makers that use the MEO Interface and reached the Exchange's top tier for the Trading Permit fee for June 2022, one (1) Market Maker was only a Member of the Exchange and not its two affiliates, MIAX and MIAX Emerald. The above data evidences that a Market Maker need not be a Member of all options exchanges, let alone the Exchange and its two affiliates, and market makers elect to do so based on their own business decisions and need to directly access each exchange's liquidity pool.

The Exchange also is not aware of any reason why a Market Maker could not cease being a permit holder in response to price increases that it deems unreasonable from its own business perspective. The Exchange does not assess any termination fee for a Member to drop its Trading Permit, nor is the Exchange aware of any other costs that would be incurred by a Market Maker to do so. Further, a broker-dealer may employ a business model that is not latency sensitive, such as one that only enters resting liquidity and, therefore, may not find interest in exchange membership. Exchange membership may also not be useful for order routing firms that seek to route orders to an exchange through another means, described below, solely as part of their best execution obligations or to comply with the trade-through requirements under Chapter XIV of the Exchange's Rules. Such broker-dealers may utilize various existing substitutes to access an exchange. For example, in lieu of becoming a member at each options exchange, a market participant may join one exchange and elect to have their orders routed in the event that a better price is available on an away market, including the Exchange. Nothing in the Order Protection Rule requires a firm to become a Member at the Exchange, or any other options exchange.[89] Further, if the Exchange is not at the NBBO, the Exchange will route an order to an away market that is at the NBBO to prevent a trade-through and also ensure that the order was executed at a superior price.[90]

Some other broker-dealers may not deem it necessary to be a Member of the Exchange and may elect to access the Exchange through other means. As a substitute for joining an exchange, a third-party may be utilized to execute an order on an exchange. For example, a third-party broker-dealer Member of the Exchange may be utilized by a retail investor to submit orders into an exchange. An institutional investor may utilize a broker-dealer, a service bureau,[91] or request sponsored access [92] through a member of an exchange in order to submit an order directly to an options exchange.[93] A market participant may either pay the costs associated with becoming a member of an exchange or, in the alternative, a market participant may elect to pay commissions to a broker-dealer, pay fees to a service bureau to submit trades, or pay a member to sponsor the market participant in order to submit trades directly to an exchange.[94] Market

[85] *See* MIAX Pearl Options Exchange Member Directory, *available at https://www.miaxoptions.com/exchange-members/pearl.*

[86] *See* NYSE American Options Membership Directory, *available at https://www.nyse.com/markets/american-options/membership* (last visited March 9, 2022); NYSE Arca Options Membership Directory, *available at https://www.nyse.com/markets/arca-options/membership* (last visited March 9, 2022); Cboe Members and Sponsored Participants, Form 1 Amendment dated February 17, 2022, Exhibit M, *available at https://www.sec.gov/Archives/edgar/vprr/2200/22000797.pdf* (last visited March 9, 2022).

[87] *See* MEMX Membership Fee Proposal, *supra* note 7.

[88] *See* Securities Exchange Act Release No. 94894 (May 11, 2022), 87 FR 29987 (May 17, 2022) (SR–BOX–2022–17) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend the Fee Schedule on the BOX Options Market LLC Facility To Adopt Electronic Market Maker Trading Permit Fees). The Exchange believes that BOX's observation demonstrates that market making firms can, and do, select which exchanges they wish to access, and, accordingly, options exchanges must take competitive considerations into account when setting fees for such access.

[89] *See* Options Order Protection and Locked/Crossed Market Plan (August 14, 2009), *available at https://www.theocc.com/getmedia/7fc629d9-4e54-4b99-9f11-c0e4db1a2266/options_order_protection_plan.pdf.*

[90] Exchange Members may elect to not route their orders by marking an order as ''do-not-route.'' In this case, the order would not be routed.

[91] Service bureaus provide access to market participants to submit and execute orders on an exchange. On the Exchange, a Service Bureau may be a Member. Some Members utilize a Service Bureau for connectivity and that Service Bureau may not be a Member. Some market participants utilize a Service Bureau who is a Member to submit orders.

[92] Sponsored Access is an arrangement whereby a member permits its customers to enter orders into an exchange's system that bypass the member's trading system and are routed directly to the Exchange, including routing through a service bureau or other third-party technology provider.

[93] This may include utilizing a Floor Broker and submitting the trade to one of the five options trading floors.

[94] The Exchange notes that it does not have insight into the economics of such a relationship where a broker-dealer utilizes another entity to access the Exchanges. It is presumed that a third-party that provides access to an exchange does so

participants may elect any of the above substitute models and weigh the varying costs when determining how to submit trades to an exchange. Depending on the number of orders to be submitted, technology, ability to control submission of orders, and projected revenues, a market participant may determine one model is more cost efficient as compared to the alternatives. The above examples clearly demonstrate competitive forces exist by the availability of ''substantially similar but not identical'' substitutable products or services to becoming a Member of the Exchange. Also, based on the disparity in amount of memberships among exchanges detailed above, numerous market participants take advantage of these substitutes to send order flow to the Exchange in lieu of becoming a Member.

Elasticity of Demand. The Exchange notes it is not aware of any reason why Members could not simply drop their access to an exchange (or not initially access an exchange) if an exchange were to establish prices for its non-transaction fees that, in the determination of such Member, did not make business or economic sense for such Member to access such exchange. The Exchange again notes that Members are not required by rule, regulation, or competitive forces to be a Member on the Exchange.

Elasticity of demand for Exchange Membership exists when it comes to purchasing a Trading Permit and, as evidenced by the below data, Members have terminated their memberships since the proposed fees were first in effect. First, and most notably, the Exchange has not seen an increase in memberships since it first adopted the proposed fee increase. In fact, three Members terminated their memberships in the time since the proposed fee increase first went into effect. In June 2021, the month immediately preceding the initial implementation of this proposed fee change, the Exchange had 20 users of the MEO Interface and 28 users of the FIX Interface. These numbers remained stagnant until August 2021, where one Member that utilized the MEO Interface ceased utilizing the MEO Interface and again in December 2021 where one Member that utilized the FIX Interface ceased utilizing the FIX Interface. These numbers again remained stagnant until March 2022, where another Member that utilized the FIX Interface ceased utilizing the FIX Interface. This resulted in 19 users of the MEO Interface and 26 users of the FIX Interface. Further, other exchanges have also experienced termination of memberships if their members deem permit or membership fees to be unreasonable or excessive. For example, the Exchange notes that a BOX participant modified its access to BOX in connection with the implementation of a proposed change to BOX's permit fees.[95] The absence of new memberships coupled with the termination of two memberships on the Exchange, as well as similar membership changes on another options exchange in relation to a trading permit fee increase, clearly shows that elasticity of demand exists.

Also, the Exchange has not experienced any Member decreasing their trading activity on the Exchange in order to move to a lower tier and be charged the corresponding lower fee. In fact, between June 2021 and July 2021, one Member that utilizes the MEO Interface moved up from Tier 1 to Tier 3 due to increasing their trading volume on the Exchange. This occurred again between January 2022 and February 2022, where another Member that utilizes the MEO Interface moved up from Tier 1 to Tier 2 also due to increasing their trading volume on the Exchange.

The Exchange has not experienced a net decrease in Members due to the fee increase, because the Exchange believes numerous considerations are taken into account when deciding to be a member of an exchange, including, but not limited to: (i) an exchange's available liquidity in options series; (ii) trading functionality, latency, reliability, throughout, access to liquidity, and determinism offered on a particular market; (iii) product offerings; (iv) customer service on an exchange; and (v) transactional pricing when socializing the change. Fees are not the sole consideration. As stated above, the Exchange socialized the proposed fee increase with Members prior to first implementing the change. During that process, some Members stated that they anticipated a potential increase due to the lower rates the Exchange historically charged.

The Proposed Fees Are Reasonable and Constrained by Similar Fees Charged by Other Options Exchanges

The proposed fees for the Exchange's Trading Permits are in line with, or cheaper than, the similar trading permit and membership fees charged by other options exchanges with similar market share. The Exchange believes other exchanges' membership and trading permit fees, even those of its affiliates, are useful examples of alternative approaches to charging for memberships and how such fees are constrained by like fees charged by other exchanges.

Again, the Exchange has not amended its Trading Permit fees since the fees were first adopted in 2018.[96] As described above, the Exchange's proposed fee increase results in fees that remain lower than those of its affiliates, MIAX and MIAX Emerald. First, MIAX and MIAX Emerald charge EEMs a similar, fixed flat trading permit fee of $1,500,[97] which equals the top tier proposed herein for users of the FIX Interface and also primarily consists of EEMs. Members that do not qualify for the top tier on the Exchange would pay a lower Trading Permit Fee than they would on MIAX or MIAX Emerald. Like the Exchange currently employs for MEO Interface, which is primarily used by Market Makers, MIAX and MIAX Emerald charge tiered trading permit fees to Market Makers. However, the Exchange's proposed fees for users of the MEO Interface are lower and range from $2,500 to $6,000, while the Trading Permit fees on MIAX and MIAX Emerald range from $7,000 to $22,000.

The below discussion illustrates how the Exchange has historically undercharged for access via Trading Permits as compared to other options exchanges. As discussed further above, the Exchange chose to charge less than other options exchanges to attract memberships and order flow as a new options exchange entrant. The Exchange now seeks to increase its Trading Permit Fees due to the maturity of its market while keeping in mind the competitive constraints based on similar fees by other options exchanges.

The proposed Trading Permit Fees compare favorably with those of other options exchanges. The Exchange proposes to charge users of the FIX Interface monthly fees ranging from

on behalf of multiple broker-dealers and provides access to multiple exchanges. It is also presumed that any increased volume that might cause such third party to achieve a higher Trading Permit pricing tier maybe offset through achieving a higher rebate on the Exchange or other economic arrangement between the parties.

[95] According to BOX, a Market Maker on BOX terminated its status as a Market Maker in response to BOX's proposed modification of Market Maker trading permit fees. *See* Securities Exchange Act Release No. 94894 (May 11, 2022), 87 FR 29987 (May 17, 2022) (SR–BOX–2022–17). BOX noted, and the Exchange agrees, that this Market Maker's decision demonstrates that Market Makers can, and do, alter their membership status if they deem permit fees at an exchange to be unsuitable for their business needs, thus demonstrating the competitive environment for Market Maker permit fees and the constraints on options exchanges when setting Market Maker permit fees.

[96] *See supra* note 9.

[97] *See* the MIAX Fee Schedule, Section (3)(b) and MIAX Emerald Fee Schedule, Section (3)(b), *available at https://www.miaxoptions.com/fees* (last visited June 30, 2022).

$500 to $1,500 based on trading volume. Users of the FIX Interface are primarily EEMs, which generally consist of order flow providers. Cboe charges monthly electronic trading permit fees based on the category of participant, such as $3,000 for Electronic Access Permit holders and $2,000 for Clearing TPH Permit holders (the Exchange notes that it only charges $250 per month for EEM Clearing Firms). Cboe's Electronic Access Permit fee is the analog to the Exchange's Trading Permit fee for Members that use the FIX Interface and is higher than the Exchange's proposed highest tier.

The Exchange's proposed monthly Trading Permit Fees for users of the MEO Interface, which are primarily Market Makers, range from $2,500 to $6,000 based on trading volume. Basing such fees on trading volume is analogous to other options exchanges that base their similar fees charged to Market Makers based on the number of options classes assigned. For example, NYSE Arca charges Market Makers a base fee of $8,000 and charges additional fees ranging from $500 to $6,000 on top of the base fee and depending on the options issues assigned, could result in monthly options trading permit fees ranging from $8,000 to $26,000 (or higher), which is higher than the Exchange's highest proposed tier of $6,000. NYSE American charges electronic Market Makers a base fee of $8,000 and charges additional fees ranging from $500 to $6,000 on top of the base fee and depending on the options issues assigned, which could result in monthly options trading permit fees ranging from $8,000 to $26,000 (or higher), also higher than the Exchange's highest proposed tier of $6,000.

The proposed Trading Permit Fee also compares favorably with those of other options exchanges with similar market share. Under the Exchange's tiered structure, a Member may trade approximately 106,000 more ADV contracts on the Exchange than on Cboe BZX Options [98] and continue to qualify for the Exchange's lowest Tier. For example, a Member would qualify for Tier 1 of the Exchange's tiered pricing structure where that Member's total volume as a percentage of TCV is between 0.00% and 0.30%. Assuming an average of 37 million contracts are traded each day during a month that Member would qualify for Tier 1 where that Member traded less than an ADV of 111,000 contracts and be charged $500 for the month, the same fee as Cboe BZX Options, where that Member connects via FIX.[99] On Cboe BZX Options, the Exchange understands that same member would no longer qualify for their lowest tier when their ADV equals or exceeds 5,000 contracts and be charged a fee of $1,000 for that month.[100]

Like the Exchange, BOX also employs a tier pricing structure for market maker trading permit fees charging $4,000 to $10,000 per month based on options classes traded.[101] BOX's pricing structure is the analog for the Exchange's Trading Permit Fees for users of the MEO Interface as that interface is primarily used by Market Makers. BOX's lowest tier only equals the Exchange's second tier for the MEO interface and its third and fourth tier exceed the Exchange's highest tier.

The Proposed Fees Are Equitable and Not Unfairly Discriminatory

The Exchange believes that the proposed monthly Trading Permit fees are not unfairly discriminatory because they would be assessed equally across all Members or firms that seek to become Members. The Exchange first adopted its tiered pricing structure in 2018 and has not amended the volume requirement since, nor does it propose to do so herein. Nonetheless, the Exchange continues to believe the tiered pricing structure remains not unfairly discriminatory because it is based on the amount of trading a Member conducts on the Exchange, related use of Exchange services, and the value of the Exchange's technology offering. In other words, the more a firm uses the Exchange's system, the more that firm will pay than others that use the system less. The proposed fees also remain not unfairly discriminatory because they continue to be based on the type of interface utilized and the value drawn from the use of that interface.

The tiered pricing structure remains not unfairly discriminatory because it is based on the amount of trading a Member conducts on the Exchange, related use of Exchange services, and the value of the Exchange's technology offering. The Exchange offers a premium System network, connectivity, and a highly deterministic trading environment, the cost of which per tier is in relation to the value it provides. The Exchange is recognized as a leader in network monitoring, determinism, risk protections, and network stability. For example, the Exchange experiences approximately a 95% determinism rate, system throughput of approximately 10.8 million quotes per second and average round trip latency rate of approximately 30.76 microseconds for a single quote. The Exchange provides a highly resilient trading platform that experienced 99.9999% of uptime since its inception over 5 years ago. The Exchange provides extreme performance and radical scalability designed to match the unique needs of trading differing asset class/market model combinations.

Again, Exchange systems offer two customer interfaces, FIX Interface gateway for orders, and ultra-low latency MEO Interface and data feeds with best-in-class wire order determinism. The Exchange also offers automated continuous testing to ensure high reliability, advanced monitoring and systems security, and employs a software architecture that results in minimizing the demands on power, space, and cooling while allowing for rapid scalability, resiliency and fault isolation. The Exchange also provides latency equalized cross-connects in the primary data center ensures fair and cost efficient access to the Exchange's Systems.

The tiered pricing structure represent the value of the Exchange's industry leading technology platform and is based on how frequently a Member trades on the Exchange. The more use, the more value a Member is extolling from the Exchange. The Exchange believes that a Member that qualifies for the first tier should not be charged the same as a Member that qualifies for the highest tier because the Member that qualifies for the first tier uses the Exchange less than the Member that qualifies for the highest tier. Members that qualify for the lowest tier tend to connect to the Exchange as part of their best execution obligations and generally tend to send the least amount of orders and messages over those connections.[102]

[98] Cboe BZX Options had an average daily market share of 7.95% as of June 23, 2022. *See* ''Market at a Glance'', *available at https://www.miaxoptions.com/* (last visited June 23, 2022).

[99] *See* ''Membership Fees'' section of the Cboe BZX Options Fee Schedule, *available at https://www.cboe.com/us/options/membership/fee_schedule/bzx* (last visited April 13, 2022). The Exchange understands Cboe BZX Options charges the same Membership Fee to all of its Options Members.

[100] The Exchange proposes to also charge a fee of $1,000 per month to Members that qualify for Tier 2, the same as BZX's highest tier. The Exchange acknowledges that the Exchange's Trading Permit fee would be higher than BZX where a Member qualifies for Tier 3.

[101] *See* Securities Exchange Act Release No. 94894 (May 11, 2022), 87 FR 29987 (May 17, 2022) (SR–BOX–2022–17).

[102] An EEM may satisfy its best execution obligations by using the FIX Interface, limiting their costs. Those EEMs that choose to use the MEO Interface do so for reasons other than best execution, such as the enhanced functionality provided by the MEO Interface, and the proposed fees would not serve as a barrier to satisfying best execution.

Those Members generally send fewer orders and messages to the Exchange resulting in less use of the Exchange resources. Therefore, the Trading Permit fees for those Members should rightfully be lower than others that trade on the Exchange for other reasons, such as a low-latency trading strategies that requires sending more orders and messages which, therefore, utilize a greater amount or Exchange resources and extoll great value from their use of the Exchange's industry leading technology offering.

Next, the existing tiered pricing structure remains not unfairly discriminatory because it continues to be based on the type of interface utilized and the value drawn from the use of that interface. As discussed above, both the MEO Interface and FIX Interface continue to be available to all Members and each Member may choose which interface to utilize based on their own business needs. The FIX Interface is the industry-wide uniform message format and provides lower bandwidth, less capacity, and fewer Exchange resources. EEMs, who are primarily order flow providers, are the primary users of the FIX Interface. Meanwhile, the MEO Interface is the more robust interface offering lower latency and higher throughput. Market Makers primarily use the MEO Interface due to its functionality, robustness, lower latency, and higher throughput and utilizes greater Exchange resources due to the increased volume of message traffic that travel through the MEO Interface.

As stated above, the Exchange offers three time-in-force modifiers: Day, IOC, and GTC. While all order types are available for use on either interface, only the time-in-force modifiers of IOC and Day are available on the MEO Interface. Market Makers utilize the time-in-force of Day on orders to be posted on the MIAX Pearl Options Book and to meet Market Makers' continuous quoting obligations under Exchange Rule 605(d). Other Market Makers, and certain EEMs, that primarily remove liquidity tend to be more latency sensitive and utilize the time-in-force of IOC on orders when looking to remove liquidity from the MIAX Pearl Options Book. The MEO Interface allows the submission of Cancel-Replacement orders, which allow for the immediate cancellation of a previously received order and the replacement of that order with a new order with new terms and conditions. Cancel-Replacement orders are primarily used by Market Makers as part of their continuous quoting obligations. Market Makers, and certain EEMs, are the primary users of the MEO Interface due to its lower latency, higher throughput, available time-in-force instructions and order types that assist them in satisfying their market making obligations. The Exchange also offers its Aggregate Risk Manager (''ARM'') over the MEO Interface and it is available to both EEMs and Market Makers.[103]

The FIX Interface provides lower capacity and bandwidth and, therefore, utilizes less Exchange resources. The FIX Interface is primarily used by EEMs, who tend to be less latency sensitive and submit less orders and messages than Market Makers. The FIX Interface provides EEMs all the functionality necessary for them to satisfy their best execution obligations. However, EEMs may choose to use the MEO Interface due to its lower latency, higher throughput, available functionality based on their business needs if they choose.

The Exchange notes that while Market Maker users of the MEO Interface continue to account for a vast majority of the increased System usage placed on the Exchange, Market Makers continue to be valuable market participants on the exchanges as the options market is a quote driven industry. The Exchange recognizes the value that Market Makers bring to the Exchange. The Exchange proposes higher, separate fees for users of the MEO Interface that are more aligned with the costs and resources that Market Makers continue to place on the Exchange and its systems.

The Exchange notes that Market Makers are the predominant users of the MEO Interface and consume the most bandwidth and resources of the network, transact the vast majority of the volume on the Exchange, and require the high touch network support services provided by the Exchange and its staff. The Exchange notes that users of the FIX Interface, *i.e.,* non-Market Makers, take up significantly less Exchange resources as discussed further below. Further, the Exchange notes that MEO users account for greater than 99% of message traffic over the network, while FIX users account for less than 1% of message traffic over the network. In the Exchange's experience, most Exchange Members do not have a business need for the high performance network solutions, like MEO, required by Market Makers and certain EEMs.

Over the period from March 2022 through May 2022, the Exchange processed 1.3 billion messages via the FIX Interface (0.33% of total messages received). Over that same time period, the Exchange processed 386.1 billion messages (99.67% of total messages received) over the MEO Interface. This marked difference between the number of FIX and MEO messages processed, when mapped to servers, software, storage, and networking results in a much higher allocation of total resources to support the MEO Interface. For one, the Exchange expends greater resources to maintain the resilience of the MEO Interface to ensure its ongoing operation in accordance with Regulation SCI. Another, the Exchange must expand its storage capacity to retain these increased messages in compliance with its record keeping obligations. The Exchange must also expend additional resources to surveil and ensure proper regulatory oversight of this increased message traffic. These pulls on Exchange resources have only increased since it first adopted the Trading Permit fee in March of 2018 [104] when the Exchange's trading volume for that month averaged 3.94%.[105] Today, the Exchange's average daily trading volume for June 2022 is 4.92%.[106] This additional volume increases the pull on Exchange resources necessary to surveil and regulate its market while also procuring additional capacity to store and monitor those messages in compliance with its record keeping obligations under the Exchange Act.

Users of the MEO Interface, therefore, receive greater value than Users of the FIX Interface due to its higher throughput, lower latency, and available functionality. As the above data shows, the Exchange also expends much more resources to support the MEO Interface than it does to support the FIX Interface. The existing tiered pricing structure is designed to account for these facts. Trading Permit fees for Members who connect through the MEO Interface are, therefore, higher than the Trading Permit fees for Members who connect through the FIX Interface. The tiered pricing structure also accounts for the corresponding use of the MEO and FIX Interfaces and charges more for those that use either interface more in terms of trading volume and proportionate pull on Exchange resources. Therefore, the proposed monthly Trading Permit fees are not unfairly discriminatory because they would be assessed equally across all Members based on the type of interface and related usage of Exchange resources.

The tiered pricing structure has been in place since 2018 [107] and similar

[103] *See* Exchange Rules 517(A) (Aggregated Risk Manager for EEMs) *and* 517B (Aggregate Risk Manager for Market Makers).

[104] *See supra* note 9.

[105] *See* Market at a Glance, *supra* note 8.

[106] *Id.*

[107] *See supra* note 9.

membership pricing structures utilized by other options exchanges assess permit fees at different rates, based upon a member's participation on that exchange,[108] and, as such, this concept is not new or novel. The Exchange also notes the some options exchanges employ a tiered pricing structure for membership fees based on options assigned or traded while the Exchange employs a tier pricing structure based on trading volume. The Exchange believes both are analogous and lead to the same result. Also see the BZX example explained above.

The proposed fees are equitable and not unfairly discriminatory as the fees apply equally to all Members. As such, all similarly situated Members, with the same trading volume, will be subject to the same Trading Permit fee. The Exchange also believes that assessing lower fees to Members with less trading volume is reasonable and appropriate as it will allow the Exchange to retain and attract smaller-scale Members, which are an integral component of the options industry marketplace. Since these smaller Members utilize less bandwidth and capacity on the Exchange's network due to the lower trading volume, the Exchange believes it is reasonable and appropriate to offer Members a lower fee. Furthermore, the Exchange tiered pricing is beneficial and valued by smaller Market Makers who provide liquidity in less liquid options classes. The Exchange fears that without its tiered pricing structure, smaller Market Makers would discontinue their membership and cease providing much needed liquidity in less liquid options classes to the detriment of all market participants. The Exchange must, therefore, consider Members' ability to discontinue their memberships when considering any potential changes to its tiered volume requirements and that Members' ability to transition to another exchange they view offers more attractive volume thresholds and pricing. The proposed fees, therefore, represent the equitable allocation of reasonable dues, fees and other charges because the fees are generally lower than other exchanges and the proposed tiered fees are similar to other tiered pricing structures on other options exchanges.[109]

Removal of Monthly Volume Credit and Trading Permit Fee Credit

The Exchange believes its proposal to remove the Monthly Volume Credit is reasonable, equitable and not unfairly discriminatory because all market participants will no longer be offered the ability to achieve the extra credits associated with the Monthly Volume Credit for submitting Priority Customer volume to the Exchange and access to the Exchange is offered on terms that are not unfairly discriminatory. The Exchange believes it is equitable and not unfairly discriminatory to remove the Monthly Volume Credit from the Fee Schedule for business and competitive reasons. The Exchange established the Monthly Volume Credit when it first launched operations to encourage Members to increase their order flow by providing a credit to those that exceeded a volume threshold. The Exchange believes that the Exchange's existing Priority Customer rebates and fees will continue to allow the Exchange to remain highly competitive and continue to attract order flow and maintain market share even without the Monthly Volume Credit.[110]

The Exchange believes its proposal to remove the Trading Permit fee credit for Members that connect via both the MEO Interface and FIX Interface is reasonable, equitable and not unfairly discriminatory because all market participants will no longer be offered the ability to receive the credit and access to the Exchange is offered on terms that are not unfairly discriminatory. The Exchange believes it is equitable and not unfairly discriminatory to remove the Trading Permit fee credit for business and competitive reasons. The Exchange established the Trading Permit fee credit to lower the costs for Members that connect via the MEO Interface and/or FIX Interface as a means to attract order flow and memberships after the Exchange first launched operations. The Exchange now believes that it is appropriate to remove this credit in light of the current operating conditions and membership on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, [111] the Exchange believes that the proposed rule change would not impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange believes the removal of the Monthly Volume Credit and Trading Permit fee credit will not place certain market participants at a relative disadvantage to other market participants because, in order to attract order flow when the Exchange first launched operations, the Exchange established these credits to lower the initial fixed cost for Members. The Exchange now believes that it is appropriate to remove this credit in light of the current operating conditions, including the Exchange's overall membership and the current type and amount of volume executed on the Exchange. The Exchange believes that the Exchange's rebates and fees will still allow the Exchange to remain highly competitive such that the Exchange should continue to attract order flow and maintain market share.

As described above, the Exchange's proposed Trading Permit fees are lower than or similar to the cost of membership and trading permits on other exchanges,[112] and therefore, may stimulate intramarket competition by attracting additional firms to become Members on the Exchange or at least should not deter interested participants from joining the Exchange. In addition, membership and trading permit fees are subject to competition from other exchanges. Accordingly, if the changes proposed herein are unattractive to market participants, it is likely the Exchange will see a decline in membership as a result. As stated above, the number of FIX and MEO Interface users remained stagnant until August 2021, where one Member that utilized the MEO Interface ceased utilizing that interface and again in December 2021, where one Member that utilized the FIX Interface ceased utilizing that interface.

The Exchange also does not believe charging different fees for MEO and FIX

[108] *See e.g.,* Securities Exchange Act Release No. 94894 (May 11, 2022), 87 FR 29987 (May 17, 2022) (SR–BOX–2022–17). NYSE Arca Options Fees and Charges, p.1 (assessing market makers $6,000 for up to 175 option issues, an additional $5,000 for up to 350 option issues, an additional $4,000 for up to 1,000 option issues, an additional $3,000 for all option issues on the exchange, and an additional $1,000 for the fifth trading permit and for each trading permit thereafter); NYSE American Options Fee Schedule, p. 23 (assessing market makers $8,000 for up to 60 plus the bottom 45% of option issues, an additional $6,000 for up to 150 plus the bottom 45% of option issues, an additional $5,000 for up to 500 plus the bottom 45% of option issues, and additional $4,000 for up to 1,100 plus the bottom 45% of option issues, an additional $3,000 for all issues traded on the exchange, and an additional $2,000 for 6th to 9th ATPs; plus an addition fee for premium products). See also BZX Options assesses the Participant Fee, which is a membership fee, according to a member's ADV. See Cboe BZX Options Exchange Fee Schedule under ''Membership Fees''. The Participant Fee is $500 if the member ADV is less than 5000 contracts and $1,000 if the member ADV is equal to or greater than 5,000 contracts.

[109] The Exchange does not charge a separate fee to Market Makers for options assignments.

[110] *See* the Exchange's Fee Schedule *available at https://www.miaxoptions.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Options_Fee_Schedule_07122022.pdf.*

[111] 15 U.S.C. 78f(8).

[112] *See supra* notes 38–46.

Interface users and basing the amount of such fees on trading volume would impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the FIX Interface is the uniform industry message protocol used by most exchanges and provides lower throughput and bandwidth than the MEO Interface. Users are free to use either interface based on their business need and the pricing structure is aligned with the interface used, its pull on Exchange resources, and the Member's monthly trading volume. The tiered pricing structure is based on the type of interface and trading volume in place on the Exchange today and the Exchange does not propose to amend the volume requirements associated with each Tier. Rather, it is simply seeking to amend the associated fees. Basing such fees on trading volume would may also stimulate intramarket competition because it is analogous to other exchanges that base like fees on options classes traded or assigned. A Member may cease being a Member if they believe the tiered structure is not appropriate or that another exchange presents a better value. Likewise, a market participant that is not already a Member may cease membership on another exchange or become a Member of MIAX Pearl where they deem the Exchange's Trading Permit fee to be a better value based on its trading activity and business needs.

Inter-Market Competition

The Exchange operates in a highly competitive market in which market participants can readily favor one of the 15 competing options venues if they deem fee levels at a particular venue to be excessive. Based on publicly-available information, and excluding index-based options, no single exchange has more than approximately 16% market share. Therefore, no exchange possesses significant pricing power regarding memberships or in the execution of multiply-listed equity and ETF options order flow. Over the course of 2021 and 2022, the Exchange's market share has fluctuated between approximately 3–6% of the U.S. equity options industry.[113] The Exchange is not aware of any evidence that a market share of approximately 3–6% provides the Exchange with anti-competitive pricing power when it comes to competition for memberships. The Exchange believes that the ever-shifting market share among exchanges from month to month demonstrates that market participants can discontinue memberships in response to fee changes. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract and retain memberships on the Exchange.

The proposed fee change will not impact intermarket competition because it will apply to all Members equally. Also, Members are free to use either the FIX or MEO Interface and may choose the interface that better meets their business needs based on their trading models and behavior. The Exchange operates in a highly competitive market in which market participants can determine whether or not to join the Exchange based on the value received compared to the cost of joining and maintaining membership on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange responded to comment letters in a prior proposal.[114]

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[115] and Rule 19b–4(f)(2)[116] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PEARL–2022–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–PEARL–2022–30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PEARL–2022–30 and should be submitted on or before August 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[117]

J. Matthew DeLesDernier,

Deputy Secretary.

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[113] *See supra* note 8.

[114] *See supra* note 55.

[115] 15 U.S.C. 78s(b)(3)(A)(ii).

[116] 17 CFR 240.19b–4(f)(2).

[117] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95424; File No. SR–NYSEAMER–2022–19]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1, To Add Subparagraph (f)(4) Regarding Directed Orders to NYSE American Rule 7.31E

August 4, 2022.

I. Introduction

On April 20, 2022, NYSE American LLC (''NYSE American'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to introduce Directed Orders. The proposed rule change was published for comment in the **Federal Register** on May 3, 2022.[3] On June 16, 2022, the Commission extended to August 7, 2022, the time period in which to approve the proposal, disapprove the proposal, or institute proceedings to determine whether to approve or disapprove the proposal.[4] On July 28, 2022, the Exchange filed Amendment No. 1 to the proposed rule change with the Commission and submitted Amendment No. 1 for inclusion in the public comment file.[5] The Commission is publishing notice of the filing of Amendment No. 1 to solicit comment from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.[6]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 94840 (May 3, 2022), 87 FR 27677 (May 9, 2022) (SR–NYSEAMER–2022–19) (''Notice'').

[4] *See* Securities Exchange Act Release No. 95117 (June 16, 2022), 87 FR 37543 (June 23, 2022).

[5] In Amendment No. 1, the Exchange: (i) represents that Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement; and (ii) updates the anticipated implementation date of the proposed rule change from the second quarter to the third quarter of 2022. *See* Letter from Martha Redding, Associate General Counsel, NYSE American LLC, to Secretary, Commission (July 28, 2022). Amendment No. 1 is available at *https://www.sec.gov/comments/sr-nyseamer-2022-19/srnyseamer202219-20135100-306080.pdf.*

[6] The Commission received one comment letter that is not germane to the proposal. *See https://www.sec.gov/comments/sr-nyseamer-2022-19/srnyseamer202219-289426.htm.*

II. Self-Regulatory Organization's Description of the Proposal, as Modified by Amendment No. 1

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify Rule 7.31E (Orders and Modifiers) to add new subparagraph (f)(4) to provide for Directed Orders and to make other conforming changes to its Rules in connection with the addition of this new order type on the Exchange. The Directed Order, as further defined below, would be an order sent to the Exchange to be routed directly to an alternative trading system (''ATS'') specified by an ATP Holder.[7]

The Exchange proposes to add Rule 7.31E(f)(4), which would define a Directed Order as a Limit Order with instructions to route on arrival at its limit price to a specified ATS with which the Exchange maintains an electronic linkage. Proposed Rule 7.31E(f)(4) would further provide that Directed Orders would be available for all securities eligible to trade on the Exchange. Proposed Rule 7.31E(f)(4) would also provide that a Directed Order would not be assigned a working time or interact with interest on the Exchange Book. The Exchange also proposes to provide in Rule 7.31E(f)(4) that the ATS to which a Directed Order is routed would be responsible for validating whether the order is eligible to be accepted, and if such ATS determines to reject the order, the order would be cancelled.

Proposed Rule 7.31E(f)(4)(A) would provide that a Directed Order must be designated for the Exchange's Core Trading Session, as defined in Rule 7.34E(a)(2).[8]

Proposed Rule 7.31E(f)(4)(A) would further provide that a Directed Order must be designated with a Time in Force modifier of IOC [9] or Day [10] and would be routed to the specified ATS with such modifier. The Exchange proposes that a Directed Order designated IOC would be traded in whole or in part on the ATS to which it is routed after receipt of the order, and any untraded quantity would be cancelled. The Exchange proposes that a Directed Order designated Day would expire at the end of the Core Trading Session on the day it is entered. Proposed Rule 7.31E(f)(1)(A) would also provide that a Directed Order may not be designated with any other modifiers defined in Rule 7.31E.

Proposed Rule 7.31E(f)(4)(B) would provide that a Directed Order in a security that is having its initial listing on the Exchange would be rejected if received before the IPO Auction concludes.

Proposed Rule 7.31E(f)(4)(C) would provide that, during a trading halt or pause, an incoming Directed Order would be rejected.

Proposed Rule 7.31E(f)(4)(D) would provide that a request to cancel a Directed Order designated Day would be routed to the ATS to which the order was routed.

The Exchange also proposes a conforming change to Rule 7.19E (Pre-Trade Risk Controls). The Exchange proposes to modify Rule 7.19E(a)(5), which sets forth the definition of Gross Credit Risk Limit and currently provides that unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37E(a)(1), and executed orders are included for purposes of calculating the Gross Credit Risk Limit. The Exchange proposes to modify Rule 7.19E(a)(5) to specify that orders routed on arrival pursuant to Rule 7.31E(f)(4) would also be included for purposes of the Gross Credit Risk Limit calculation.

The Exchange believes that the proposed rule change would facilitate additional trading opportunities by

[7] Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement.

[8] Because the Exchange proposes that Directed Orders may only be designated for the Core Trading Session, the Exchange also proposes conforming changes to Rule 7.34E (Trading Sessions). Specifically, the Exchange proposes to modify Rule 7.34E(c)(1)(E) to provide that Directed Orders designated for the Early Trading Session would be rejected and Rule 7.34E(c)(3)(C) to provide that Directed Orders designated for the Late Trading Session would be rejected. The Exchange also proposes an additional change to correct a typographical error in Rule 7.34E(c)(1), to update the reference to ''paragraphs (c)(1)(A)–(E)'' to ''paragraphs (c)(1)(A)–(F)'' to accurately reflect the number of subparagraphs under Rule 7.34E(c)(1).

[9] *See* Rule 7.31E(b)(2), which provides that a Limit Order may be designated with an Immediate-or-Cancel (''IOC'') modifier.

[10] *See* Rule 7.31E(b)(1), which provides that orders may be designated with a Day modifier, and that an order to buy or sell designated Day, if not traded, will expire at the end of the designated session on the day on which it was entered.

offering ATP Holders the ability to designate orders submitted to the Exchange to be routed to an ATS of their choosing for execution. The Exchange believes the proposed change would encourage ATP Holders to utilize the Exchange as a venue for order entry and further believes that the proposed change could create efficiencies for ATP Holders by enabling them to send orders that they wish to route to an alternate destination through the Exchange, thereby enabling them to leverage order entry protocols and specifications already configured for their interactions with the Exchange. The Exchange notes that the Directed Order, as proposed, would operate similarly to the Primary Only Order already offered by the Exchange, which is an order that is routed directly to the primary listing market on arrival, without being assigned a working time or interacting with interest on the Exchange Book.[11] The Exchange also believes that the Directed Order would offer ATP Holders functionality akin to order types and routing options that currently exist on other equities exchanges.[12]

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update.[13] Subject to effectiveness of this proposed rule change, the Exchange anticipates that the proposed change will be implemented in the third quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934,[14] in general, and furthers the objectives of Section 6(b)(5),[15] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and promote just and equitable principles of trade because the Directed Order would offer ATP Holders access to additional trading opportunities by permitting them to designate orders submitted to the Exchange to be routed directly to a specified ATS for execution. The Exchange further believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market by offering ATP Holders the option to send orders that they wish to route to an alternate destination for execution through the Exchange, which would create efficiencies to the extent ATP Holders are able to leverage existing protocols and specifications. Finally, the Exchange notes that the proposed functionality is not novel, as both the Exchange and other exchanges offer their members functionality whereby an exchange routes orders on behalf of a member to a specified trading center without such order interacting with the exchange's book.[16]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rules governing Directed Orders would promote competition because they would provide for an order type on the Exchange that would facilitate additional trading opportunities for market participants. The Exchange further believes that the proposed rules would allow it to offer ATP Holders functionality similar to order types and routing options that exist on other equities exchanges, thereby enabling the Exchange to compete with such exchanges.[17]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Discussion and Commission Findings

After careful review of the proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[18] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[19] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to

[11] *See* Rule 7.31E(f)(1). NYSE American also offers variations of the Primary Only Order, including the Primary Only Until 9:45 Order, which is a Limit or Inside Limit Order that, on arrival and until 9:45 a.m. Eastern Time, routes to the primary listing market, and the Primary Only Until 3:55 Order, which is a Limit or Inside Limit Order entered on the Exchange until 3:55 p.m. Eastern Time, after which time the order is cancelled on the Exchange and routed to the primary listing market. *See* Rules 7.31E(f)(2) and (f)(3). The Exchange's affiliated exchanges NYSE Arca, Inc. (''NYSE Arca''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'') (collectively, the ''Affiliated Exchanges'') also offer the Primary Only Order and variations thereof. *See* NYSE Arca Rules 7.31–E(f)(1)–(f)(3); NYSE Chicago Rules 7.31(f)(1)–(f)(3); NYSE National Rules 7.31(f)(1)–(f)(3).

[12] *See, e.g.,* Nasdaq Stock Market LLC (''Nasdaq''), Equity 4, Equity Trading Rules, Rule 4758(a)(ix) (defining the Nasdaq Directed Order as an order designed to use a routing strategy under which the order is directed to an automated trading center other than Nasdaq, as directed by the entering party, without checking the Nasdaq Book); Cboe EDGX Exchange, Inc. (''EDGX'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGX system and is immediately routed by EDGX to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe EDGA Exchange, Inc. (''EDGA'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGA system and is immediately routed by EDGA to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe BZX Exchange, Inc. (''BZX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BZX system and be sent to a specified away trading center); Cboe BYX Exchange, Inc. (''BYX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BYX system and be sent to a specified away trading center). The Exchange also believes that the Directed Order would provide functionality similar to the C–LNK routing strategy formerly offered by EDGA, in which C–LNK orders bypassed EDGA's local book and routed directly to a specified Single Dealer Platform destination. *See* Securities Exchange Act Release No. 82904 (March 20, 2018), 83 FR 12995 (March 26, 2018) (SR–CboeEDGA–2018–004) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Expand an Offering Known a Cboe Connect To Provide Connectivity to Single-Dealer Platforms Connected to the Exchange's Network and To Propose a Per Share Executed Fee for Such Service).

[13] The Exchange will also provide information regarding the ATS(s) to which a Directed Order may be designated to route by Trader Update.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] *See* notes 11 & 12, *supra.*

[17] *See* note 12, *supra.*

[18] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 15 U.S.C. 78f(b)(5).

remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and that the rules of a national securities exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission finds that the proposed rule change is reasonably designed to remove impediments to and perfect the mechanism of a free and open market and a national market system because it would provide ATP Holders with additional trading opportunities by providing them with the option to designate orders to be routed by the Exchange directly to a specified ATS for execution. The use of Directed Orders would be voluntary, and the Exchange represents that it would not direct orders to any ATSs with which the Exchange has a financial relationship. The Commission also believes that the proposed rule change would not permit unfair discrimination among customers, brokers, or dealers because Directed Orders will be available to all ATP Holders on an equal basis. Finally, the Commission believes that the proposed changes to Exchange Rule 7.19E(a)(5) will ensure that Directed Orders are included in the calculation of Gross Credit Risk Limit.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2022–19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2022–19. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2022–19 and should be submitted on or before August 31, 2022.

V. Accelerated Approval of Amendment No. 1

As noted above,[20] in Amendment No. 1, as compared to the original proposal,[21] the Exchange: (i) represents that Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement; and (ii) updates the anticipated implementation date of the proposed rule change from the second quarter to the third quarter of 2022. The Commission finds that Amendment No. 1 to the proposal raises no novel regulatory issues, that it is reasonably designed to protect investors and the public interest, and that it is consistent with the requirements of the Act. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[22] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[23] that the proposed rule change (SR–NYSEAMER–2022–19), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

J. Matthew DeLesDernier,

Deputy Secretary.

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[20] *See supra* note 5.

[21] *See* Notice, *supra* note 3.

[22] 15 U.S.C. 78s(b)(2).

[23] 15 U.S.C. 78s(b)(2).

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95426; File No. SR–NYSENAT–2022–06]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1, To Add Subparagraph (f)(4) Regarding Directed Orders to NYSE National Rule 7.31

August 4, 2022.

I. Introduction

On April 20, 2022, NYSE National, Inc. (''NYSE National'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to introduce Directed Orders. The proposed rule change was published for comment in the **Federal Register** on May 4, 2022.[3] On June 16, 2022, the Commission extended to August 8, 2022, the time period in which to approve the proposal, disapprove the proposal, or institute proceedings to determine whether to approve or disapprove the proposal.[4] On July 28, 2022, the Exchange filed Amendment No. 1 to the proposed rule change with the Commission and submitted Amendment No. 1 for inclusion in the public comment file.[5]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 94842 (May 4, 2022), 87 FR 28041 (May 10, 2022) (SR–NYSENAT–2022–06) (''Notice'').

[4] *See* Securities Exchange Act Release No. 95114 (June 16, 2022), 87 FR 37538 (June 23, 2022).

[5] In Amendment No. 1, the Exchange: (i) represents that Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement; and (ii) updates the anticipated implementation date of the proposed rule change from the second quarter to the third quarter of 2022. *See* Letter from Martha Redding, Associate General Counsel, NYSE National, Inc., to Secretary, Commission (July 28, 2022). Amendment No. 1 is available at *https://www.sec.gov/comments/sr-nysenat-2022-06/srnysenat202206-20135098-306078.pdf.*

The Commission has received no comment letters on the proposed rule change. The Commission is publishing notice of the filing of Amendment No. 1 to solicit comment from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Self-Regulatory Organization's Description of the Proposal, as Modified by Amendment No. 1

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify Rule 7.31 (Orders and Modifiers) to add new subparagraph (f)(4) to provide for Directed Orders and to make other conforming changes to its Rules in connection with the addition of this new order type on the Exchange. The Directed Order, as further defined below, would be an order sent to the Exchange to be routed directly to an alternative trading system (''ATS'') specified by an ETP Holder.[6]

The Exchange proposes to add Rule 7.31(f)(4), which would define a Directed Order as a Limit Order with instructions to route on arrival at its limit price to a specified ATS with which the Exchange maintains an electronic linkage. Proposed Rule 7.31(f)(4) would also provide that Directed Orders would be available for all securities eligible to trade on the Exchange and would not be assigned a working time or interact with interest on the Exchange Book. The Exchange also proposes to provide in Rule 7.31(f)(4) that the ATS to which a Directed Order is routed would be responsible for validating whether the order is eligible to be accepted, and if such ATS determines to reject the order, the order would be cancelled.

Proposed Rule 7.31(f)(4)(A) would provide that a Directed Order must be designated for the Exchange's Core Trading Session, as defined in Rule 7.34(a)(2).[7]

Proposed Rule 7.31(f)(4)(A) would further provide that a Directed Order must be designated with a Time in Force modifier of IOC[8] or Day[9] and would be routed to the specified ATS with such modifier. The Exchange proposes that a Directed Order designated IOC would be traded in whole or in part on the ATS to which it is routed after receipt of the order, and any untraded quantity would be cancelled. The Exchange proposes that a Directed Order designated Day would expire at the end of the Core Trading Session on the day it is entered. Proposed Rule 7.31(f)(1)(A) would also provide that a Directed Order may not be designated with any other modifiers defined in Rule 7.31.

Proposed Rule 7.31(f)(4)(B) would provide that, during a trading halt or pause, an incoming Directed Order would be rejected.

Proposed Rule 7.31(f)(4)(C) would provide that a request to cancel a Directed Order designated Day would be routed to the ATS to which the order was routed.

The Exchange also proposes a conforming change to Rule 7.19 (Pre-Trade Risk Controls). The Exchange proposes to modify Rule 7.19(a)(5), which sets forth the definition of Gross Credit Risk Limit and currently provides that unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37(a)(1), and executed orders are included for purposes of calculating the Gross Credit Risk Limit. The Exchange proposes to modify Rule 7.19(a)(5) to specify that orders routed on arrival pursuant to Rule 7.31(f)(4) would also be included for purposes of the Gross Credit Risk Limit calculation.

The Exchange believes that the proposed rule change would facilitate additional trading opportunities by offering ETP Holders the ability to designate orders submitted to the Exchange to be routed to an ATS of their choosing for execution. The Exchange believes the proposed change would encourage ETP Holders to utilize the Exchange as a venue for order entry and further believes that the proposed change could create efficiencies for ETP Holders by enabling them to send orders that they wish to route to an alternate destination through the Exchange, thereby enabling them to leverage order entry protocols and specifications already configured for their interactions with the Exchange. The Exchange notes that the Directed Order, as proposed, would operate similarly to the Primary Only Order already offered by the Exchange, which is an order that is routed directly to the primary listing market on arrival, without being assigned a working time or interacting with interest on the Exchange Book.[10] The Exchange also believes that the Directed Order would offer ETP Holders functionality akin to order types and routing options that currently exist on other equities exchanges.[11]

[6] Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement.

[7] Because the Exchange proposes that Directed Orders may only be designated for the Core Trading Session, the Exchange also proposes conforming changes to Rule 7.34 (Trading Sessions). Specifically, the Exchange proposes to modify Rule 7.34(c)(1)(E) to provide that Directed Orders designated for the Early Trading Session would be rejected and Rule 7.34(c)(3)(C) to provide that Directed Orders designated for the Late Trading Session would be rejected.

[8] *See* Rule 7.31(b)(2), which provides that a Limit Order may be designated with an Immediate-or-Cancel (''IOC'') modifier.

[9] *See* Rule 7.31(b)(1), which provides that orders may be designated with a Day modifier, and that an order to buy or sell designated Day, if not traded, will expire at the end of the designated session on the day on which it was entered.

[10] *See* Rule 7.31(f)(1). NYSE National also offers variations of the Primary Only Order, including the Primary Only Until 9:45 Order, which is a Limit or Inside Limit Order that, on arrival and until 9:45 a.m. Eastern Time, routes to the primary listing market, and the Primary Only Until 3:55 Order, which is a Limit or Inside Limit Order entered on the Exchange until 3:55 p.m. Eastern Time, after which time the order is cancelled on the Exchange and routed to the primary listing market. *See* Rules 7.31(f)(2) and (f)(3). The Exchange's affiliated exchanges NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), and NYSE Chicago, Inc. (''NYSE Chicago'') (collectively, the ''Affiliated Exchanges'') also offer the Primary Only Order and variations thereof. *See* NYSE American Rules 7.31E(f)(1)–(f)(3); NYSE Arca Rules 7.31–E(f)(1)–(f)(3); NYSE Chicago Rules 7.31(f)(1)–(f)(3).

[11] *See, e.g.,* Nasdaq Stock Market LLC (''Nasdaq''), Equity 4, Equity Trading Rules, Rule 4758(a)(ix) (defining the Nasdaq Directed Order as an order designed to use a routing strategy under which the order is directed to an automated trading center other than Nasdaq, as directed by the entering party, without checking the Nasdaq Book); Cboe EDGX Exchange, Inc. (''EDGX'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGX system and is immediately routed by EDGX to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe EDGA Exchange, Inc. (''EDGA'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGA system and is immediately routed by EDGA to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe BZX Exchange, Inc. (''BZX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BZX system and be sent to a specified away trading center); Cboe BYX Exchange, Inc. (''BYX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under

Continued

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update.[12] Subject to effectiveness of this proposed rule change, the Exchange anticipates that the proposed change will be implemented in the third quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934,[13] in general, and furthers the objectives of Section 6(b)(5),[14] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and promote just and equitable principles of trade because the Directed Order would offer ETP Holders access to additional trading opportunities by permitting them to designate orders submitted to the Exchange to be routed directly to a specified ATS for execution. The Exchange further believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market by offering ETP Holders the option to send orders that they wish to route to an alternate destination for execution through the Exchange, which would create efficiencies to the extent ETP Holders are able to leverage existing protocols and specifications. Finally, the Exchange notes that the proposed functionality is not novel, as both the Exchange and other exchanges offer their members functionality whereby an exchange routes orders on behalf of a member to a specified trading center without such order interacting with the exchange's book.[15]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rules governing Directed Orders would promote competition because they would provide for an order type on the Exchange that would facilitate additional trading opportunities for market participants. The Exchange further believes that the proposed rules would allow it to offer its ETP Holders functionality similar to order types and routing options that exist on other equities exchanges, thereby enabling the Exchange to compete with such exchanges.[16]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Discussion and Commission Findings

After careful review of the proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[17] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[18] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and that the rules of a national securities exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission finds that the proposed rule change is reasonably designed to remove impediments to and perfect the mechanism of a free and open market and a national market system because it would provide Participants with additional trading opportunities by providing them with the option to designate orders to be routed by the Exchange directly to a specified ATS for execution. The use of Directed Orders would be voluntary, and the Exchange represents that it would not direct orders to any ATSs with which the Exchange has a financial relationship. The Commission also believes that the proposed rule change would not permit unfair discrimination among customers, brokers, or dealers because Directed Orders will be available to all ETP Holders on an equal basis. Finally, the Commission believes that the proposed changes to Exchange Rule 7.19(a)(5) will ensure that Directed Orders are included in the calculation of Gross Credit Risk Limit.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2022–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2022–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule

which an ISO order would bypass the BYX system and be sent to a specified away trading center). The Exchange also believes that the Directed Order would provide functionality similar to the C–LNK routing strategy formerly offered by EDGA, in which C–LNK orders bypassed EDGA's local book and routed directly to a specified Single Dealer Platform destination. *See* Securities Exchange Act Release No. 82904 (March 20, 2018), 83 FR 12995 (March 26, 2018) (SR-CboeEDGA–2018–004) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Expand an Offering Known a Cboe Connect To Provide Connectivity to Single-Dealer Platforms Connected to the Exchange's Network and To Propose a Per Share Executed Fee for Such Service).

[12] The Exchange will also provide information regarding the ATS(s) to which a Directed Order may be designated to route by Trader Update.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] *See* notes 10 & 11, *supra.*

[16] *See* note 11, *supra.*

[17] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 15 U.S.C. 78f(b)(5).

change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2022–06 and should be submitted on or before August 31, 2022.

V. Accelerated Approval of Amendment No. 1

As noted above,[19] in Amendment No. 1, as compared to the original proposal,[20] the Exchange: (i) represents that Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement; and (ii) updates the anticipated implementation date of the proposed rule change from the second quarter to the third quarter of 2022. The Commission finds that Amendment No. 1 to the proposal raises no novel regulatory issues, that it is reasonably designed to protect investors and the public interest, and that it is consistent with the requirements of the Act. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[21] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[22] that the proposed rule change (SR–NYSENAT–2022–06), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

[19] *See supra* note 5.

[20] *See* Notice, *supra* note 3.

[21] 15 U.S.C. 78s(b)(2).

[22] 15 U.S.C. 78s(b)(2).

[23] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17102 Filed 8–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34662; File No. 812–14387]

CION Investment Corporation, et al

August 4, 2022.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

APPLICANTS: CION Investment Corporation, CION Investment Management, LLC, CION Investment Partners I, L.P. and CION Management, LLC.

FILING DATES: The application was filed on November 14, 2014, and amended on June 9, 2015, September 23, 2015, January 22, 2016, April 26, 2016, February 27, 2019, July 24, 2019, October 23, 2019, January 27, 2020, May 29, 2020, September 24, 2020, February 18, 2022, May 19, 2022 and July 13, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below.

Hearing requests should be received by the Commission by 5:30 p.m. on August 29, 2022, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: *Legal@cioninvestments.com.*

FOR FURTHER INFORMATION CONTACT: Asen Parachkevov, Senior Counsel, or Trace Rakestraw, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' thirteenth amended and restated application, dated July 13, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at, at *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17114 Filed 8–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95420; File No. SR–MEMX–2022–19]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule To Adopt Market Data Fees

August 4, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 22, 2022, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Members [3] and non-Members (the ''Fee Schedule'') pursuant to Exchange Rules 15.1(a) and (c). The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal immediately.

The Exchange previously filed the proposal on March 24, 2022 (SR–MEMX–2022–03) (the ''Initial Proposal''). The Exchange withdrew the Initial Proposal and replaced the proposal with SR–MEMX–2022–14 (the ''Second Proposal''). The Exchange has withdrawn the Second Proposal and is replacing it with the current filing (SR–MEMX–2022–19). The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

The purpose of the proposed rule change is to amend the Fee Schedule to adopt fees the Exchange will charge to Members and non-Members for each of its three proprietary market data feeds, namely MEMOIR Depth, MEMOIR Top, and MEMOIR Last Sale (collectively, the ''Exchange Data Feeds''). As set forth below, the Exchange believes that the proposed fees are fair and reasonable and has based its proposal on the fact that competitive forces exist with respect to the Exchange Data Feeds, the fact that the Exchange Data Feeds are optional data products for which there are substitutes, and a comparison to competitor pricing. The Exchange is proposing to implement the proposed fees immediately.

Before setting forth the additional details regarding the proposal, immediately below is a description of the proposed fees.

Proposed Market Data Pricing

The Exchange offers three separate data feeds to subscribers—MEMOIR Depth, MEMOIR Top and MEMOIR Last Sale. The Exchange notes that there is no requirement that any Firm subscribe to a particular Exchange Data Feed or any Exchange Data Feed whatsoever, but instead, a Firm may choose to maintain subscriptions to those Exchange Data Feeds they deem appropriate based on their business model. The proposed fee will not apply differently based upon the size or type of Firm, but rather based upon the subscriptions a Firm has to Exchange Data Feeds and their use thereof, which are in turn based upon factors deemed relevant by each Firm. The proposed pricing for each of the Exchange Data Feeds is set forth below.

MEMOIR Depth

The MEMOIR Depth feed is a MEMX-only market data feed that contains all displayed orders for securities trading on the Exchange (*i.e.,* top and depth-of-book order data), order executions (*i.e.,* last sale data), order cancellations, order modifications, order identification numbers, and administrative messages.[4] The Exchange proposes to charge each of the fees set forth below for MEMOIR Depth.

1. *Internal Distribution Fee.* For the receipt of access to the MEMOIR Depth feed, the Exchange proposes to charge $1,500 per month. This proposed access fee would be charged to any data recipient that receives a data feed of the MEMOIR Depth feed for purposes of internal distribution (*i.e.,* an ''Internal Distributor''). The Exchange proposes to define an Internal Distributor as ''a Distributor that receives an Exchange Data product and then distributes that data to one or more data recipients within the Distributor's own organization.'' [5] The proposed access fee for internal distribution will be charged only once per month per subscribing entity (''Firm''). The Exchange notes that it has proposed to use the phrase ''own organization'' in the definition of Internal Distributor and External Distributor because a Firm will be permitted to share data received from an Exchange Data product to other legal entities affiliated with the Firm that have been disclosed to the Exchange without such distribution being considered external to a third party. For instance, if a company has multiple affiliated broker-dealers under the same holding company, that company could have one of the broker-dealers or a non-broker-dealer affiliate subscribe to an Exchange Data product and then share the data with other affiliates that have a need for the data. This sharing with affiliates would not be considered external distribution to a third party but instead would be considered internal distribution to data recipients within the Distributor's own organization.

2. *External Distribution Fee.* For redistribution of the MEMOIR Depth feed, the Exchange proposes to establish an access fee of $2,500 per month. The proposed redistribution fee would be charged to any External Distributor of the MEMOIR Depth feed, which would be defined to mean ''a Distributor that receives an Exchange Data product and then distributes that data to a third party or one or more data recipients outside the Distributor's own organization.'' [6] The proposed access fee for external distribution will be charged only once per month per Firm. As noted above, while a Firm will be permitted to share data received from an Exchange Data product to other legal entities affiliated with the Firm that have been disclosed to the Exchange without such distribution being considered external to a third party, if a Firm distributes data received from an Exchange Data product to an unaffiliated third party that would be considered distribution to data recipients outside the Distributor's own organization and the access fee for external distribution would apply.

3. *Non-Display Use Fees.* The Exchange proposes to establish separate non-display fees for usage by Trading Platforms and other Users (*i.e.,* not by Trading Platforms).[7] Non-Display Usage

[3] *See* Exchange Rule 1.5(p).

[4] *See* MEMX Rule 13.8(a).

[5] *See* Market Data Definitions under the proposed MEMX Fee Schedule. The Exchange also proposes to adopt a definition for ''Distributor'', which would mean any entity that receives an Exchange Data product directly from the Exchange or indirectly through another entity and then distributes internally or externally to a third party.

[6] *See* Market Data Definitions under the proposed MEMX Fee Schedule.

[7] The Exchange proposes to define a Trading Platform as ''any execution platform operated as or by a registered National Securities Exchange (as defined in Section 3(a)(1) of the Exchange Act), an Alternative Trading System (as defined in Rule 300(a) of Regulation ATS), or an Electronic

would be defined to mean ''any method of accessing an Exchange Data product that involves access or use by a machine or automated device without access or use of a display by a natural person or persons.'' [8] For Non-Display Usage of the MEMOIR Depth feed not by Trading Platforms, the Exchange proposes to establish a fee of $1,500 per month.[9] For Non-Display Usage of the MEMOIR Depth feed by Trading Platforms, the Exchange proposes to establish a fee of $4,000 per month. The proposed fees for Non-Display Usage will be charged only once per category per Firm.[10] In other words, with respect to Non-Display Usage Fees, a Firm that uses MEMOIR Depth for non-display purposes but does not operate a Trading Platform would pay $1,500 per month, a Firm that uses MEMOIR Depth in connection with the operation of one or more Trading Platforms (but not for other purposes) would pay $4,000 per month, and a Firm that uses MEMOIR Depth for non-display purposes other than operating a Trading Platform and for the operation of one or more Trading Platforms would pay $5,500 per month.

4. *User Fees.* The Exchange proposes to charge a Professional User Fee (per User) of $30 per month and a Non-Professional User Fee (per User) of $3 per month. The proposed User fees would apply to each person that has access to the MEMOIR Depth feed for displayed usage. Thus, each Distributor's count will include every individual that accesses the data regardless of the purpose for which the individual uses the data. Internal Distributors and External Distributors of the MEMX Depth feed must report all Professional and Non-Professional Users in accordance with the following:

• In connection with a Distributor's distribution of the MEMOIR Depth feed, the Distributor must count as one User each unique User that the Distributor has entitled to have access to the MEMOIR Depth feed.

• Distributors must report each unique individual person who receives access through multiple devices or multiple methods (*e.g.,* a single User has multiple passwords and user identifications) as one User.

• If a Distributor entitles one or more individuals to use the same device, the Distributor must include only the individuals, and not the device, in the count. Thus, Distributors would not be required to report User device counts associated with a User's display use of the data feed.

5. *Enterprise Fee.* Other than the Digital Media Enterprise Fee described below, the Exchange is not proposing to adopt an Enterprise Fee for the MEMOIR Depth feed at this time.

6. *Digital Media Enterprise Fee.* As an alternative to User fees, a recipient Firm may purchase a monthly Digital Media Enterprise license to receive MEMOIR Depth for distribution to an unlimited number of Users for viewing via television, websites, and mobile devices for informational and non-trading purposes only. The Exchange proposes to establish a fee of $5,000 per month for a Digital Media Enterprise license to the MEMOIR Depth feed.

MEMOIR Top

The MEMOIR Top feed is a MEMX-only market data feed that contains top of book quotations based on equity orders entered into the System as well as administrative messages.[11]

The Exchange proposes to charge each of the fees set forth below for MEMOIR Top.

1. *Internal Distribution Fee.* For the receipt of access to the MEMOIR Top feed, the Exchange proposes to charge $750 per month. This proposed access fee would be charged to any data recipient that receives a data feed of the MEMOIR Top feed for purposes of internal distribution (*i.e.,* an Internal Distributor). The proposed access fee for internal distribution will be charged only once per month per Firm.

2. *External Distribution Fee.* For redistribution of the MEMOIR Top feed, the Exchange proposes to establish an access fee of $2,000 per month. The proposed redistribution fee would be charged to any External Distributor of the MEMOIR Top feed. The proposed access fee for external distribution will be charged only once per month per Firm.

3. *Non-Display Use Fees.* The Exchange does not propose to establish non-display fees for usage by Trading Platforms or other Users with respect to MEMOIR Top.

4. *User Fees.* The Exchange proposes to charge a Professional User Fee (per User) of $0.01 per month and a Non-Professional User Fee (per User) of $0.01 per month. The proposed User fees would apply to each person that has access to the MEMOIR Top feed that is provided by an External Distributor for displayed usage. The Exchange does not propose any per User fees for internal distribution of the MEMOIR Top feed. Each External Distributor's count will include every individual that accesses the data regardless of the purpose for which the individual uses the data. External Distributors of the MEMOIR Top feed must report all Professional and Non-Professional Users [12] in accordance with the following:

• In connection with an External Distributor's distribution of the MEMOIR Top feed, the Distributor must count as one User each unique User that the Distributor has entitled to have access to the MEMOIR Top feed.

• External Distributors must report each unique individual person who receives access through multiple devices or multiple methods (*e.g.,* a single User has multiple passwords and user identifications) as one User.

• If an External Distributor entitles one or more individuals to use the same device, the Distributor must include only the individuals, and not the device, in the count. Thus, Distributors would not be required to report User device counts associated with a User's display use of the data feed.

5. *Enterprise Fee.* As an alternative to User fees, a recipient Firm may purchase a monthly Enterprise license to receive MEMOIR Top for distribution to an unlimited number of Professional and Non-Professional Users. The Exchange proposes to establish a fee of $10,000 per month for an Enterprise license to the MEMOIR Top feed.

6. *Digital Media Enterprise Fee.* As an alternative to User fees, a recipient Firm may purchase a monthly Digital Media Enterprise license to receive MEMOIR Top for distribution to an unlimited number of Users for viewing via television, websites, and mobile devices

Communications Network (as defined in Rule 600(b)(23) of Regulation NMS).'' *See* Market Data Definitions under the proposed MEMX Fee Schedule.

[8] *See* Market Data Definitions under the proposed MEMX Fee Schedule.

[9] Non-Display Usage not by Trading Platforms would include trading uses such as high frequency or algorithmic trading as well as any trading in any asset class, automated order or quote generation and/or order pegging, price referencing for smart order routing, operations control programs, investment analysis, order verification, surveillance programs, risk management, compliance, and portfolio management.

[10] The Exchange proposes to adopt note 1 to the proposed Market Data fees table, which would make clear to subscribers that use of the data for multiple non-display purposes or operate more than one Trading Platform would only be charged once per category per month. Thus, the footnote makes clear that each fee applicable to Non-Display Usage is charged per subscriber (*e.g.,* a Firm) and that each of the fees represents the maximum charge per month per subscriber regardless of the number of non-display uses and/or Trading Platforms operated by the subscriber, as applicable.

[11] *See* MEMX Rule 13.8(b).

[12] The Exchange notes that while it is not differentiating Professional and Non-Professional Users based on fees (in that it is proposing the same fee for such Users) for this data feed, and thus will not audit Firms based on this distinction, it will request reporting of each distinct category for informational purposes.

for informational and non-trading purposes only. The Exchange proposes to establish a fee of $2,000 per month for a Digital Media Enterprise license to the MEMOIR Top feed.

MEMOIR Last Sale

The MEMOIR Last Sale feed is a MEMX-only market data feed that contains only execution information based on equity orders entered into the System as well as administrative messages.[13] The Exchange proposes to charge each of the fees set forth below for MEMOIR Last Sale.

1. *Internal Distribution Fee.* For the receipt of access to the MEMOIR Last Sale feed, the Exchange proposes to charge $500 per month. This proposed access fee would be charged to any data recipient that receives a data feed of the MEMOIR Last Sale feed for purposes of internal distribution (*i.e.,* an Internal Distributor). The proposed access fee for internal distribution will be charged only once per month per Firm.

2. *External Distribution Fee.* For redistribution of the MEMOIR Last Sale feed, the Exchange proposes to establish an access fee of $2,000 per month. The proposed redistribution fee would be charged to any External Distributor of the MEMOIR Last Sale feed. The proposed access fee for external distribution will be charged only once per month per Firm.

3. *Non-Display Use Fees.* The Exchange does not propose to establish separate non-display fees for usage by Trading Platforms or other Users with respect to MEMOIR Last Sale.

4. *User Fees.* The Exchange proposes to charge a Professional User Fee (per User) of $0.01 per month and a Non-Professional User Fee (per User) of $0.01 per month. The proposed User fees would apply to each person that has access to the MEMOIR Last Sale feed that is provided by an External Distributor for displayed usage. The Exchange does not propose any per User fees for internal distribution of the MEMOIR Last Sale feed. Each External Distributor's count will include every individual that accesses the data regardless of the purpose for which the individual uses the data. External Distributors of the MEMOIR Last Sale feed must report all Professional and Non-Professional Users [14] in accordance with the following:

- In connection with an External Distributor's distribution of the MEMOIR Last Sale feed, the Distributor must count as one User each unique User that the Distributor has entitled to have access to the MEMOIR Last Sale feed.
- External Distributors must report each unique individual person who receives access through multiple devices or multiple methods (*e.g.,* a single User has multiple passwords and user identifications) as one User.
- If an External Distributor entitles one or more individuals to use the same device, the Distributor must include only the individuals, and not the device, in the count. Thus, Distributors would not be required to report User device counts associated with a User's display use of the data feed.

5. *Enterprise Fee.* As an alternative to User fees, a recipient Firm may purchase a monthly Enterprise license to receive MEMOIR Last Sale for distribution to an unlimited number of Professional and Non-Professional Users. The Exchange proposes to establish a fee of $10,000 per month per Firm for an Enterprise license to the MEMOIR Last Sale feed.

6. *Digital Media Enterprise Fee.* As an alternative to User fees, a recipient Firm may purchase a monthly Digital Media Enterprise license to receive MEMOIR Last Sale for distribution to an unlimited number of Users for viewing via television, websites, and mobile devices for informational and non-trading purposes only. The Exchange proposes to establish a fee of $2,000 per month per Firm for a Digital Media Enterprise license to the MEMOIR Last Sale feed.

Additional Discussion—Competitive Forces and Availability of Substitutes

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [15] As the Commission itself recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [16] Indeed, equity trading is currently dispersed across 16 exchanges,[17] 31 alternative trading systems,[18] and numerous broker-dealer internalizers and wholesalers, all competing for order flow. While the competitive environment described above and the Commission's statements related thereto are primarily regarding market share and trading volumes, and not market data specifically, the Exchange believes that competition does constrain the Exchange's ability to set market data prices, as described below.

The recent growth of MEMX's market share demonstrates the competitive marketplace in which the Exchange operates. The Exchange launched in September 2020 and slowly grew over the next several months as it completed its staged rollout intended to ensure market stability. In January 2021, the Exchange averaged approximately 0.6% of consolidated trading volume. [19] The Exchange experienced significant growth every month from February 2021 to December 2021 and ended 2021 with market share of approximately 4.2% of consolidated volume; MEMX has maintained a similar market share percentage in 2022, with approximately 3.95% market share through the first half of the year.[20]

As the Exchange's transaction market share has increased, so has the value of its market data. In addition to achieving approximately 4% of consolidated volume, the Exchange's NBBO Quote Market Share (*i.e.,* the notional value displayed at the inside national best bid or offer, or ''NBBO'', as a percentage of overall notional value at the NBBO) is comparable to that of Cboe BZX Exchange, Inc. (''BZX'') and the New York Stock Exchange (''NYSE''), and higher than that of Cboe EDGX Exchange. Inc.[21] The Exchange determined the level of the fees to charge for the Exchange Data Feeds

[13] *See* MEMX Rule 13.8(c).

[14] *See supra* note 12.

[15] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS Adopting Release'').

[16] *See* Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Transaction Fee Pilot for NMS Stocks Final Rule) (''Transaction Fee Pilot'').

[17] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at: *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[18] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsData.* A list of alternative trading systems registered with the Commission is available at: *https://www.sec.gov/foia/docs/atslist.htm.*

[19] Market share percentage calculated as of June 30, 2022. The Exchange receives and processes data made available through consolidated data feeds (*i.e.,* CTS and UTDF).

[20] *See id.*

[21] *See* Cboe Global Markets NBBO Quote Market Share Statistics, available at: *https://www.cboe.com/us/equities/market_statistics/.* In June 2022, NBBO Quote Market Share of the largest six equities exchanges was as follows: NYSE Arca 18.54%, Nasdaq 17.76%, NYSE 11.47%, BZX 11.4%, MEMX 10.06%, EDGX 8.92%. The remaining ten equities exchanges have NBBO Quote Market Share below 5%.

based on the Exchange's belief in the value of the Exchange's market data. In particular, as noted elsewhere in this proposal, the proposed fee structure is comparable to that of BZX and the proposed fees themselves are equal to or in many cases lower than BZX. Thus, as the Exchange has similar market quality to BZX and other larger maker/taker exchanges and has priced its data at a significant discount to those markets, the Exchange believes it is starting from a place of general acceptability to industry participants.

As noted above, in less than two years, MEMX has grown from 0% to approximately 4% market share of consolidated trading volume. During that same period, the Exchange has had a steady increase in the number of subscribers to Exchange Data Feeds. As a new entrant into the exchange industry, the Exchange is particularly subject to competitive forces as it works to attract new Members and trading volume and maintain participation from existing participants. While the Exchange has been able to rapidly grow its market share since its launch in September 2020, MEMX operates only a single U.S. equities exchange with market share that remains significantly lower than the market share of the largest exchange groups. As noted above, until April of this year, MEMX did not charge fees for market data provided by the Exchange. The objective of this approach was to eliminate any fee-based barriers for Members when MEMX launched as a national securities exchange in 2020, which the Exchange believes has been helpful in its ability to attract order flow as a new exchange. The Exchange also did not initially charge for market data because MEMX believes that any exchange should first deliver meaningful value to Members and other market participants before charging fees for its products and services. The Exchange believes that its proposed approach to market data fees is reasonable based on the existence of competition, the existence of substitutes, and a comparison to competitors.

The Exchange is not required to make the Exchange Data Feeds available or to offer any specific pricing alternatives to any customers, nor is any firm required to purchase the Exchange Data Feeds. Firms that choose to subscribe to the Exchange Data Feeds do so for the primary goals of using it to increase their revenues, reduce their expenses, and in some instances to compete directly with the Exchange (including for order flow). Those firms are able to determine for themselves whether or not the Exchange Data Feeds or any other similar products are attractively priced.

Because the Exchange Data Feeds have not been previously subject to fees, the Exchange did not know the impact of the proposed fees on data recipients at the time of the Initial Proposal but expected that subscribers may choose to reduce or eliminate their use of MEMX data. The Exchange now has additional data regarding the impact of fees for Exchange Data Feeds. Specifically, current subscribers to the Exchange Data Feeds have indeed changed their behavior in response to the imposition of fees as predicted in the Initial Proposal. Following the date that fees for the Exchange Data Feeds were officially announced, fifteen (15) out of seventy-nine (79) subscribers, representing 19% of the subscribers to such data feeds, modified or canceled their subscriptions before the fees went into effect. In each instance, the subscriber told the Exchange that the reason for modifying or cancelling its subscription was the imminent imposition of fees. These modifications and cancellations are evidence that subscribing to the Exchange Data Feeds is discretionary, that each customer makes the decision whether to subscribe based on its own analysis of the benefits and costs to itself, and that customers can and do make those decisions quickly based on reactions to fee changes. Prior to the imposition of fees, four (4) customers (or 5% of market data subscribers) informed the Exchange that if the Exchange imposes the fees as proposed, such customers will limit their subscription the MEMOIR Top feed and/or the MEMOIR Last Sale feed, rather than the MEMOIR Depth feed, which is more expensive under the proposed fees. Notably, three (3) of these customers are active trading participants on the Exchange and have continued to participate on the Exchange without use of the Exchange's MEMOIR Depth feed. In addition, eleven (11) customers of the Exchange that were subscribed to receive Exchange Data Feeds have cancelled their subscriptions to such data feeds entirely (representing approximately 14% of market data subscribers). Five (5) of the eleven (11) customers that have cancelled all subscriptions to Exchange Data Feeds actively trade on the Exchange and have informed the Exchange that they will rely instead on consolidated data distributed pursuant to NMS Plans (*i.e.,* ''SIP data'') to participate on the Exchange. This is clear evidence that the availability of these substitute products constrains the Exchange's ability to charge supra-competitive prices for the Exchange Data Feeds.[22]

The Exchange intentionally adopted fees that it believed were reasonable and would not result in the Exchange losing market share. In fact, despite the modifications and cancellations described above, the Exchange has not lost market share from such market participants. Rather, their participation has remained similar to that on the Exchange prior to the imposition of fees and resulting changes to their market data subscriptions. However, the Exchange continues to believe that a data recipient that chose to discontinue subscribing to the Exchange's Data Feeds could also choose to shift order flow away from the Exchange and, given the current competitive environment, if data recipients had both discontinued the product and shifted order flow away from the Exchange, the Exchange would have had to reevaluate the fees and file a separate proposed rule change to amend its fees. The Exchange believes that the majority of data subscribers have maintained both their subscriptions to Exchange Data Feeds and their market share on the Exchange due to the overall reasonability of the proposed fees.

Had the proposed fees for the Exchange Data Feeds instead been unreasonable, the Exchange believes it would have seen additional modifications or cancellations to subscriptions to the Exchange Data Feeds and this may have further resulted in a loss of market share. As the Exchange has intentionally avoided imposing unreasonable fees, consistent with its obligations as a registered national securities exchange, the Exchange cannot present statistical evidence to support its understanding of how market participants would have reacted to the imposition of such fees. Indeed, adopting fees that are unreasonable in order to prove that the Exchange's market data is subject to competitive forces, would contradict the Exchange's responsibilities under Section 6(b)(4) of the Exchange Act, and would have the paradoxical effect of weakening competition in the market by harming the competitive standing of a new exchange entrant that has actively sought to increase competition among U.S. equities exchanges.

[22] The Exchange notes that the remaining customers that modified or cancelled their subscriptions to the Exchange Data Feeds (seven customers total) are not trading participants on the Exchange and likely subscribed to the Exchange Data Feeds initially because they were free but determined to cancel such subscriptions now that the Exchange is charging market data fees.

Additional Discussion—Comparison With Other Exchanges

The proposed fee structure is not novel but is instead comparable to the fee structure currently in place for the equities exchanges operated by Cboe Global Markets, Inc., in particular BZX.[23] As noted above, in January 2022, MEMX had 4.2% market share; for that same month, BZX had 5.5% market share.[24] The Exchange is proposing fees for its Exchange Data Feeds that are similar in structure to BZX and rates that are equal to, or in most cases lower, than the rates data recipients pay for comparable data feeds from BZX.[25] The Exchange notes that other competitors maintain fees applicable to market data that are considerably higher than those proposed by the Exchange, including NYSE Arca[26] and Nasdaq.[27] However, the Exchange has focused its comparison on BZX because it is the closest market in terms of market share and offers market data at prices lower than several other incumbent exchanges.[28]

The fees for the BZX Depth feed—which like the MEMOIR Depth feed, includes top of book, depth of book, trades, and security status messages—consist of an internal distributor access fee of $1,500 per month (the same as the Exchange's proposed rate), an external distributor access fee of $5,000 per month (two times the Exchange's proposed rate), a non-display usage fee for non-Trading Platforms of $2,000 per month ($500 more than the Exchange's proposed rate), a non-display usage fee for Trading Platforms of $5,000 per month ($1,000 more than the Exchange's proposed rate), a Professional User fee (per User) of $40 per month ($10 more than the Exchange's proposed rate), and a Non-Professional User fee (per User) of $5 per month ($2 more than the Exchange's proposed rate).[29]

The comparisons of the MEMOIR Last Sale feed and MEMOIR Top feed to the BZX Last Sale feed and BZX Top feed, respectively, are similar in that BZX generally maintains the same fee structure proposed by the Exchange and BZX charges fees that are comparable to, but in most cases higher than, the Exchange's proposed fees. Notably, the User fees proposed by the Exchange for External Distributors of MEMOIR Last Sale and MEMOIR Top ($0.01 for both Professional Users and Non-Professional Users) are considerably lower than those charged by BZX for BZX Top and BZX Last Sale ($4 for Professional Users and $0.10 for Non-Professional Users).

By charging the same low rate for all Users of MEMOIR Top and MEMOIR Last Sale the Exchange believes it is proposing a structure that is not only lower cost but that will also simplify reporting for subscribers who externally distribute these data feeds to Users, as the Exchange believes that categorization of Users as Professional and Non-Professional is not meaningful for these products and requiring such categorization would expose Firms to unnecessary audit risk of paying more for mis-categorization. However, the Exchange does not believe this is equally true for MEMOIR Depth, as most individual Users of MEMOIR Depth are likely to be Professional Users and the Exchange has proposed pricing for such Users that the Exchange believes is reasonable given the value to Professional Users (*i.e.,* since Professional Users use data to participate in the markets as part of their full-time profession and earn compensation based on their employment). While the Exchange would prefer the simplicity of a single fee, similar to that imposed for Professional Users and Non-Professional Users, as that would reduce audit risk and simplify reporting, the proposed fee for Professional Users if also applied to Non-Professional Users would be significantly higher than other exchanges charge. The Exchange reiterates that it does not anticipate many Non-Professional Users to subscribe to MEMOIR Depth. In fact, the Exchange is only aware of a single Non-Professional User (*i.e.,* one User) that is reported to receive MEMOIR Depth.

Additional Discussion

In general, the Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. Accordingly, in proposing to charge fees for market data,

[23] *See* BZX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[24] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[25] The Exchange notes that although no fee proposed by the Exchange is higher than the fee charged for BZX for a comparable data product, under certain fact patterns a BZX data recipient could pay a lower rate than that charged by the Exchange. For instance, while the Exchange has proposed to adopt identical fees to those charged for internal distribution of MEMOIR Top as compared to BZX Top ($750 per month) and for internal distribution of MEMOIR Last Sale as compared to BZX Last Sale ($500 per month), BZX permits a data recipient who takes both feeds to pay only one fee and, upon request, to receive the other data feed free of charge. *See* BZX Fee Schedule, Market Data Fees, BZX Depth, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.* Because the Exchange has not proposed such a discount, a data recipient taking both MEMOIR TOP and MEMOIR Last Sale would pay more ($1,250 per month) than they would to take comparable data feeds from BZX ($750 per month).

[26] Fees for the NYSE Arca Integrated Feed, which is the comparable product to MEMOIR Depth, are $3,000 for access (internal use) and $3,750 for redistribution (external distribution), compared to the Exchange's proposed fees of $1,500 and $2,500, respectively. In addition, for its Integrated Feed, NYSE Arca charges for three different categories of non-display usage, each of which is $10,500 and each of which can be charged to the same firm more than one time (*e.g.,* a customer operating a Trading Platform would pay $10,500 compared to the Exchange's proposed fee of $4,000 but would also pay for each Trading Platform, up to three, if they operate more than one, instead of the single fee proposed by the Exchange; if that customer also uses the data for the other categories of non-display usage they would also pay $10,500 for each other category of usage, whereas the Exchange would only charge $1,500 for any non-display usage other than operating a Trading Platform). Finally, the NYSE Arca Integrated Feed user fee for pro devices is $60 compared to the proposed Professional User fee of $30 for MEMOIR Depth and the NYSE Arca Integrated user fee for non-pro devices is $20 compared to the proposed Non-Professional User fee of $3 for MEMOIR Depth. *See* NYSE Proprietary Market Data Pricing list, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf.*

[27] Fees for the Nasdaq TotalView data feed, which is the comparable product to MEMOIR Depth, are $1,500 for access (internal use) and $3,750 for redistribution (external distribution), compared to the Exchange's proposed fees of $1,500 and $2,500, respectively. In addition, for TotalView, Nasdaq charges Trading Platforms $5,000 compared to the Exchange's proposal of $4,000, and, like NYSE Arca, charges customers per Trading Platform, up to three, if they operate more than one, instead of the single fee proposed by the Exchange. Nasdaq also requires users to report and pay usage fees for non-display access at levels of from $375 per subscriber for smaller firms with 39 or fewer subscribers to $75,000 per firm for a larger firm with over 250 subscribers. The Exchange does not require counting of devices or users for non-display purposes and instead has proposed flat fee of $1,500 for non-display usage not by Trading Platforms. Finally, the Nasdaq TotalView user fee for professional subscribers is $76 compared to the proposed Professional User fee of $30 for MEMOIR Depth and the Nasdaq TotalView user fee for non-professional subscribers is $15 compared to the proposed Non-Professional User fee of $3 for MEMOIR Depth. *See* Nasdaq Global Data Products pricing list, available at: *http://www.nasdaqtrader.com/TraderB.aspx?id=MDDPricingALLN.*

[28] *See supra* notes 26 and 27.

[29] *See* BZX Fee Schedule, Market Data Fees, BZX Depth, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.* The Exchange notes that there are differences between the structure of BZX Depth fees and the proposed fees for MEMOIR Depth, including that the Exchange has proposed a Digital Media Enterprise License for MEMOIR Depth but a comparable license is not available from BZX. Additionally, BZX maintains a general enterprise license for User fees, similar to that proposed by the Exchange for MEMOIR Top and MEMOIR Last Sale, but the Exchange has not proposed adding a general Enterprise license at this time.

the Exchange has sought to be especially diligent in transparently assessing the impact on Members—both generally and in relation to other Members, *i.e.,* to assure the fee will not create a financial burden on any participant and will not have an undue impact in particular on smaller Members and competition among Members in general. The Exchange believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1) under the Act,[30] and Rule 19b–4 thereunder,[31] with respect to the types of information self-regulatory organizations (''SROs'') should provide when filing fee changes, and Section 6(b) of the Act,[32] which requires, among other things, that exchange fees be reasonable and equitably allocated,[33] not designed to permit unfair discrimination,[34] and that they not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[35] This rule change proposal addresses those requirements, and the analysis and data in this section are designed to clearly and comprehensively show how they are met.[36]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b) [37] of the Act in general, and furthers the objectives of Section 6(b)(4) [38] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. Additionally, the Exchange believes that the proposed fees are consistent with the objectives of Section 6(b)(5) [39] of the Act in that they are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to a free and open market and national market system, and, in general, to protect investors and the public interest, and, particularly, are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Proposed Rule Change Is Reasonable

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [40]

With respect to market data, the decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC* upheld the Commission's reliance on the existence of competitive market mechanisms to evaluate the reasonableness and fairness of fees for proprietary market data:

In fact, the legislative history indicates that the Congress intended that the market system ''evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed'' and that the SEC wield its regulatory power ''in those situations where competition may not be sufficient,'' such as in the creation of a ''consolidated transactional reporting system.'' [41]

The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' '' [42]

In this competitive marketplace, the Exchange's executed trading volume has grown from 0% market share to approximately 4% market share in less than two years and the Exchange believes that it is reasonable to begin charging fees for the Exchange Data Feeds. One of the primary objectives of MEMX is to provide competition and to reduce fixed costs imposed upon the industry. Consistent with this objective, the Exchange believes that this proposal reflects a simple, competitive, reasonable, and equitable pricing structure, with fees that are discounted when compared to products and services offered by competitors.[43]

The Exchange is not aware of any evidence that a market share of approximately 4% provides the Exchange with supra-competitive pricing power because, as shown elsewhere, market participants (even those that trade on the Exchange) are not required to subscribe to the Exchange Data Feeds, and if they do so, have a choice with respect to the Exchange Data Feed(s) to which they will subscribe. As noted above, when the Exchange announced that it would charge for the Exchange Data Feeds, 19% of its subscribers either modified or cancelled their subscriptions to Exchange Data Feeds. While some of these subscribers do not actively participate by trading on the Exchange and likely subscribed to the Exchange Data Feeds because they were offered free of charge, several of the subscribers that modified or cancelled their subscriptions are in fact Members that trade on the Exchange. Specifically, five (5) subscribers that actively participate on the Exchange have cancelled all subscriptions to the Exchange Data Feeds and have informed the Exchange that they will instead utilize SIP data to trade on the Exchange. In addition, three (3) subscribers that actively participate on the Exchange have discontinued their subscription to receive the MEMOIR Depth feed and have informed the Exchange that they will instead use the less expensive MEMOIR Top feed to trade on the Exchange (the Exchange notes that two of these subscribers have also maintained their subscriptions to the MEMOIR Last Sale feed).

With regard to reasonableness, the Exchange understands that the Commission has traditionally taken a market-based approach to examine whether the SRO making the proposal was subject to significant competitive forces in setting the terms of the proposal. In looking at this question, consistent with the decisions in

[30] 15 U.S.C. 78s(b)(1).

[31] 17 CFR 240.19b–4.

[32] 15 U.S.C. 78f(b).

[33] 15 U.S.C. 78f(b)(4).

[34] 15 U.S.C. 78f(b)(5).

[35] 15 U.S.C. 78f(b)(8).

[36] In 2019, Commission staff published guidance suggesting the types of information that SROs may use to demonstrate that their fee filings comply with the standards of the Exchange Act (''Fee Guidance''). While MEMX understands that the Fee Guidance does not create new legal obligations on SROs, the Fee Guidance is consistent with MEMX's view about the type and level of transparency that exchanges should meet to demonstrate compliance with their existing obligations when they seek to charge new fees. *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019) available at *https://www.sec.gov/tm/staff-guidancesro-rule-filings-fees.*

[37] 15 U.S.C. 78f.

[38] 15 U.S.C. 78f(b)(4).

[39] 15 U.S.C. 78f(b)(5).

[40] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37499.

[41] *NetCoalition* v. *SEC,* 615 F.3d 525, 535 (D.C. Cir. 2010) (''NetCoalition I'') (quoting H.R. Rep. No. 94–229 at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 323).

[42] *Id.* at 535.

[43] *See supra* notes 26–27; *see supra* note 29 and accompanying text.

Susquehanna Int'l Grp., LLC v. *SEC*[44] and *In the Matter of the Application of Securities Industry and Financial Markets Ass'n for Review of Action taken by NYSE Arca, Inc. and Nasdaq Stock Market, LLC,*[45] the Commission considers whether the SRO has provided evidence in its filing that: (i) there are reasonable substitutes for the product or service; (ii) ''platform'' competition constrains the ability to set the fee; and/or (iii) revenue and cost analysis shows the fee would not result in the SRO taking supra-competitive profits. If the SRO demonstrates that the fee is subject to significant competitive forces, the Commission will next consider whether there is any substantial countervailing basis to suggest the fee's terms fail to meet one or more standards under the Exchange Act. If the filing fails to demonstrate that the fee is constrained by competitive forces, the SRO must provide a substantial basis, other than competition, to show that it is consistent with the Exchange Act, which may include production of relevant revenue and cost data pertaining to the product or service.

The Exchange has not previously charged fees for market data but commenced charging in April of this year. As discussed in the purpose section of this proposed rule change, while the Exchange intentionally adopted fees that it believes are reasonable and would not result in a loss of market share, consistent with its obligations as a national securities exchange under Section 6(b)(4) of the Act, the Exchange continues to believe that competitive forces are in effect and that if the proposed fees for the Exchange Data Feeds were unreasonable that the Exchange would lose current or prospective Members and market share.

1. The Proposed Fees Are Constrained by Significant Competitive Forces

a. Exchange Market Data Fees Are Constrained by Competition

The Commission itself has recognized that the market for trading services in NMS stocks has become ''more fragmented and competitive.''[46] The Commission's Division of Trading and Markets has also recognized that with so many ''operating equities exchanges and dozens of ATSs, there is vigorous price competition among the U.S. equity markets and, as a result, [transaction] fees are tailored and frequently modified to attract particular types of order flow, some of which is highly fluid and price sensitive.''[47] Indeed, as noted above, equity trading is currently dispersed across 16 exchanges, 31 alternative trading systems, and numerous broker-dealer internalizers and wholesalers, all competing for order flow. While the competitive environment described above and the Commission's statements related thereto are primarily regarding market share and trading volumes, and not market data specifically, the Exchange believes that competition does constrain the Exchange's ability to set market data prices, as described in this proposal.

Further, low barriers to entry mean that new exchanges like the Exchange may rapidly enter the market and offer competition with the Exchange. Due to the ready availability of substitutes and the low cost to move order flow to those substitute trading venues, an exchange setting market data fees that are not at competitive levels would expect to quickly lose business to competitors with more attractive pricing. Indeed, as described above, at least eight Members trade on the Exchange either by using the lower cost MEMOIR Top feed (some in combination with MEMOIR Last Sale) or without use of any Exchange Data Feed (*i.e.,* using SIP data). Although the various exchanges may differ in their strategies for pricing their market data products and their transaction fees for trades—with some offering low-cost market data with higher trading costs, and others charging more for market data and comparatively less for trading—all exchanges compete for the same pool of customers and must work to demonstrate to such customers that pricing is reasonable. The Exchange believes that the best way to do this is to provide transparency into the costs of producing and maintaining its services.

Commission staff noted in its Fee Guidance that, as an initial step in assessing the reasonableness of a fee, staff considers whether the fee is constrained by significant competitive forces. To determine whether a proposed fee is constrained by significant competitive forces, staff has said that it considers whether the evidence demonstrates that there are reasonable substitutes for the product or service that is the subject of a proposed fee. As noted elsewhere in this proposal, there is no regulatory requirement that any market participant subscribe to any Exchange Data Feeds or a particular Exchange Data Feed. To demonstrate substitutability with tangible evidence, as noted above, five (5) Members that actively trade on the Exchange have determined to the SIPs as a substitute for the Exchange's Data Feeds but have continued trading on the Exchange while three (3) Members that actively trade on the Exchange have determined to use lower cost Exchange Data Feeds (*i.e.,* MEMOIR Top or MEMOIR Top in conjunction with MEMOIR Last Sale) instead of the MEMOIR Depth feed.

The Exchange believes the proposed fees are reasonable because in setting them, the Exchange is constrained by the availability of numerous competitors offering market data products and trading services. Such substitutes need not be identical, but only substantially similar to the product at hand. More specifically, in setting fees for the Exchange Data Feeds, the Exchange is constrained by the fact that, if its pricing is unattractive to customers, customers have their pick of alternative sources of data or a large number of alternative execution venues to use instead of the Exchange. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of competition ensures that the Exchange cannot set unreasonable market data fees without suffering the negative effects of that decision in the fiercely competitive market in which it operates.

b. Exchange Data Feeds Are Optional Market Data Products

Subscribing to the Exchange Data Feeds is entirely optional. The Exchange is not required to make the Exchange Data Feeds available to any customers, nor is any customer required to purchase any Exchange Data Feed. Unlike some other data products (*e.g.,* the consolidated quotation and last-sale information feeds) that firms are required to purchase in order to fulfill regulatory obligations,[48] a customer's decision whether to purchase any Exchange Data Feed is entirely discretionary. Most Firms that choose to subscribe to an Exchange Data Feed do so for the primary goals of using it to

[44] 866 F.3d 442 (D.C. Cir. 2017).

[45] Securities Exchange Act Release No. 84432 (October 16, 2018).

[46] *See* Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7–05–18).

[47] Commission Division of Trading and Markets, Memorandum to EMSAC, dated October 20, 2015, available here: *https://www.sec.gov/spotlight/emsac/memo-maker-taker-feeson-equities-exchanges.pdf.*

[48] The Exchange notes that broker-dealers are not required to purchase proprietary market data to comply with their best execution obligations. *See In the Matter of the Application of Securities Industry and Financial Markets Association for Review of Actions Taken by Self-Regulatory Organizations,* Release Nos. 34–72182; AP–3–15350; AP–3–15351 (May 16, 2014). Similarly, there is no requirement in Regulation NMS or any other rule that proprietary data be utilized for order routing decisions, and some competing exchanges, broker-dealers and ATSs have chosen not to do so.

increase their revenues, reduce their expenses, and in some instances to compete directly with the Exchange for order flow. Such firms are able to determine for themselves whether a particular Exchange Data Feed is necessary for their business needs, and if so, whether or not it is attractively priced. If an Exchange Data Feed does not provide sufficient value to a Firm based on the uses such Firm may have for it, such Firm may simply choose to conduct their business operations in ways that do not use the applicable Exchange Data Feed. Again, the Exchange has demonstrated above that several Members have in fact made this determination and trade on the Exchange without use of Exchange Data Feeds or with use of one or more of the lower cost Exchange Data Feeds and not MEMOIR Depth.

Specifically related to the Exchange Data Feed with the highest rates, the MEMOIR Depth Feed, even if a Firm determines that the fees for such feed are too high, customers can access much of the same data at lower rates by subscribing to the MEMOIR Top feed (which includes best-bid-and-offer information for the Exchange on a real-time basis) and MEMOIR Last Sale (which includes last-sale information for the Exchange on a real-time basis). MEMX top-of-book quotation information and last-sale information is also available on the consolidated SIP feeds.[49] In this way, MEMOIR Top, MEMOIR Last Sale, and SIP data products are all substitutes for a significant portion of the data available on the MEMOIR Depth Feed, and SIP data products are also a substitute for a significant portion of data available on the MEMOIR Top and MEMOIR Last Sale feeds. As shown above, several Members that trade on the Exchange discontinued subscriptions to MEMOIR Depth and instead use MEMOIR Top (or MEMOIR Top combined with MEMOIR Last Sale) as a substitute while others discontinued their subscription to Exchange Data Feeds altogether, using SIP data as a substitute. Furthermore, several exchange competitors of the Exchange have not subscribed to any Exchange Data Feeds for purposes of executing orders on their exchanges, order routing, and regulatory purposes.[50] As such competitors are required by Regulation NMS to honor (*i.e.,* not trade through, lock or cross) protected quotations [51] displayed by the Exchange and by rule they offer routing services including routing to the Exchange,[52] these competitors must have determined it possible to meet these obligations through use of SIP data in lieu of subscribing to any Exchange Data Feed.

The only content available on the MEMOIR Depth Feed that is not available on these other products is the order-by-order look at the MEMX order book, which provides information about depth-of-book on the Exchange. The Exchange has been a vocal advocate in support of the Commission's Market Data Infrastructure Rule, which mandates the creation of a ''SIP Premium'' product that would include depth-of-book information on the consolidated market data feeds.[53] The Exchange has also been a vocal advocate in support of pricing new content for the consolidated market data feeds in a reasonable and competitive manner that would encourage the use of a SIP Premium product and other content to be provided via the SIPs.[54] Future products such as SIP Premium would include not only integrated depth-of-book information from MEMX, but all other exchanges as well, and would further constrain the Exchange's ability to price any Exchange Data Feed, including MEMOIR Depth, at a supra-competitive price. However, even in the absence of such products, the Exchange believes that use of the Exchange Data Feeds is entirely optional, as described above.

Further, in the case of products that are also redistributed through market data vendors such as Bloomberg and Refinitiv, the vendors themselves provide additional price discipline for proprietary data products because they control the primary means of access to certain end users. These vendors impose price discipline based upon their business models. For example, vendors that assess a surcharge on data they sell are able to refuse to offer proprietary products that their end users do not or will not purchase in sufficient numbers. Even in the absence of fees for the Exchange Data Feeds, many major market data vendors have not elected to make available the Exchange Data Feeds and likely will not unless their customers request it, and customers will not elect to pay the proposed fees unless the applicable Exchange Data Feed can provide value by sufficiently increasing revenues or reducing costs to the customer's business in a manner that will offset the fees. All of these factors operate as constraints on pricing proprietary data products.

In setting the proposed fees for the Exchange Data Feeds, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of alternatives to the Exchange and the continued availability of choice between different Exchange Data Feeds, other exchanges' proprietary data products, and the SIPs ensure that the Exchange cannot set unreasonable fees when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if the attendant fees are not justified by the returns that any particular vendor or data recipient would achieve through the purchase.

2. The Proposed Fees Are Reasonable

The specific fees that the Exchange proposes for the Exchange Data Feeds are reasonable for the following additional reasons.

Overall. The Exchange believes the proposed fees for the Exchange Data Feeds are reasonable when compared to fees for comparable products, such as the BZX Depth feed, BZX Top feed, and BZX Last Sale feed, compared to which the Exchange's proposed fees are generally lower, as well as other comparable data feeds priced significantly higher than the Exchange's proposed fees for the Exchange Data Feeds.[55] Specifically with respect to the MEMOIR Depth feed, the Exchange believes that the proposed fees for such feed are reasonable because they represent not only the value of the data available from the MEMOIR Top and

[49] Broadly speaking, the self-regulatory organizations (''SROs'') administer the SIPs and set pricing. Each SIP charges its own fees, which are determined by the operating committees of each SIP subject to the SEC rule filing process. While MEMX is a member of the operating committee of each SIP, it has only one vote and does not exercise control over SIP pricing. MEMX also notes that the SIPs charge pursuant to a different pricing structure than the pricing structure proposed by the Exchange in this filing.

[50] *See, e.g.,* NYSE Arca Rule 7.37–E.(d), Order Execution and Routing, and BZX Rule 11.21, each of which discloses the data feeds used by each respective exchange and state that SIP products are used with respect to MEMX.

[51] *See* Rule 600(b)(71) of Regulation NMS, 17 CFR 242.600(b)(17).

[52] See NYSE Arca Rule 7.37–E.(b), describing routing services offered by NYSE Arca; BZX Rule 11.13(b), describing routing services offered by BZX.

[53] *See, e.g.,* Letter from Anders Franzon, General Counsel, MEMX LLC, dated May 26, 2020, regarding proposed Market Data Infrastructure rule, available at: *https://www.sec.gov/comments/s7-03-20/s70320-7235183-217090.pdf.*

[54] *See, e.g.,* Letter from Adrian Griffiths, Head of Market Structure, MEMX LLC, dated November 8, 2021, regarding proposed fees for consolidated data provided pursuant to CTA/CQ/UTP Plans, available at: *https://www.sec.gov/comments/sr-ctacq-2021-03/srctacq202103-9403088-262830.pdf.*

[55] *See supra* notes 26–27; *see supra* note 29 and accompanying text.

MEMOIR Last Sale data feeds, which have lower proposed fees, but also the value of receiving the depth-of-book data on an order-by-order basis. The Exchange believes it is reasonable to have pricing based, in part, upon the amount of information contained in each data feed and the value of that information to market participants. The MEMOIR Top and Last Sale data feeds, as described above, can be utilized to trade on the Exchange but contain less information than that is available on the MEMOIR Depth feed (*i.e.,* even for a subscriber who takes both feeds, such feeds do not contain depth-of-book information). Thus, the Exchange believes it reasonable for the products to be priced as proposed, with MEMOIR Last Sale having the lowest price, MEMOIR Top the next lowest price, and MEMOIR Depth the highest price (and more than MEMOIR Last Sale and MEMOIR Top combined).

Internal Distribution Fees. The Exchange believes that it is reasonable to charge

Fees to access the Exchange Data Feeds for Internal Distribution because of the value of such data to subscribers in their profit-generating activities. The Exchange also believes that the proposed monthly Internal Distribution fees for MEMOIR Depth, MEMOIR Top, and MEMOIR Last Sale are reasonable as they are the same amounts charged by at least one other exchange of comparable size for comparable data products,[56] and are lower than the fees charged by several other exchanges for comparable data products.[57]

External Distribution Fees. The Exchange believes that it is reasonable to charge External Distribution fees for the Exchange Data Feeds because vendors receive value from redistributing the data in their business products provided to their customers. The Exchange believes that charging External Distribution fees is reasonable because the vendors that would be charged such fees profit by re-transmitting the Exchange's market data to their customers. These fees would be charged only once per month to each vendor account that redistributes any Exchange Data Feed, regardless of the number of customers to which that vendor redistributes the data. The Exchange also believes the proposed monthly External Distribution fee for the MEMOIR Depth Feed is reasonable because it is half the amount of the fee charged by at least one other exchange of comparable size for a comparable data product,[58] and significantly less than the amount charged by several other exchanges for comparable data products.[59] Similarly, the Exchange believes the proposed monthly External Distribution fees for the MEMOIR TOP and MEMOIR Last Sale feeds are reasonable because they are discounted compared to same amounts charged by at least one other exchange of comparable size for comparable data products, and significantly less than the amount charged by several other exchanges for comparable data products.[60]

User Fees. The Exchange believes that having separate Professional and Non-Professional User fees for the MEMOIR Depth feed is reasonable because it will make the product more affordable and result in greater availability to Professional and Non-Professional Users. Setting a modest Non-Professional User fee is reasonable because it provides an additional method for Non-Professional Users to access the Exchange Data Feeds by providing the same data that is available to Professional Users. The proposed monthly Professional User fee and monthly Non-Professional User fee are reasonable because they are lower than the fees charged by at least one other exchange of comparable size for comparable data products,[61] and significantly less than the amounts charged by several other exchanges for comparable data products.[62] The Exchange also believes it is reasonable to charge the same low per User fee of $0.01 for both Professional Users and Non-Professional Users receiving the MEMOIR Top and MEMOIR Last Sale feeds, as this is not only pricing such data at a much lower cost than other exchanges charge for comparable data feeds[63] but doing so will also simplify reporting for subscribers who externally distribute these data feeds to Users, as the Exchange believes that categorization of Users as Professional and Non-Professional is not meaningful for these products and that requiring such categorization would expose Firms to unnecessary audit risk of paying more for mis-categorization. The Exchange also believes that the proposal to require reporting of individual Users, but not devices, is reasonable as this too will eliminate unnecessary audit risk that can arise when recipients are required to apply complex counting rules such as whether or not to count devices or whether an individual accessing the same data through multiple devices should be counted once or multiple times.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Usage fees for the MEMOIR Depth feed are reasonable, because they reflect the value of the data to the data recipients in their profit-generating activities and do not impose the burden of counting non-display devices.

The Exchange believes that the proposed Non-Display Usage fees reflect the significant value of the non-display data use to data recipients, which purchase such data on an entirely voluntary basis. Non-display data can be used by data recipients for a wide variety of profit-generating purposes, including proprietary and agency trading and smart order routing, as well as by data recipients that operate Trading Platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. Although some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce a recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting recipients. The Exchange believes that charging for non-trading uses is reasonable because data recipients can derive substantial value from such uses, for example, by automating tasks so that can be performed more quickly and accurately and less expensively than if they were performed manually.

Previously, the non-display use data pricing policies of many exchanges required customers to count, and the exchanges to audit the count of, the number of non-display devices used by

[56] *See* BZX Fee Schedule available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[57] *See* NYSE Proprietary Market Data Pricing list, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf;* Nasdaq Global Data Products pricing list, available at: *http://www.nasdaqtrader.com/TraderB.aspx?id=MDDPricingALLN.*

[58] *See* BZX Fee Schedule available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[59] *See id.*

[60] *See* NYSE Proprietary Market Data Pricing list, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf;* Nasdaq Global Data Products pricing list, available at: *http://www.nasdaqtrader.com/TraderB.aspx?id=MDDPricingALLN.*

[61] *See* BZX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[62] *See* NYSE Proprietary Market Data Pricing list, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf;* Nasdaq Global Data Products pricing list, available at: *http://www.nasdaqtrader.com/TraderB.aspx?id=MDDPricingALLN.*

[63] *See id.*

a customer. As non-display use grew more prevalent and varied, however, exchanges received an increasing number of complaints about the impracticality and administrative burden associated with that approach. In response, several exchanges developed a non-display use pricing structure that does not require non-display devices to be counted or those counts to be audited, and instead categorizes different types of use. The Exchange proposes to distinguish between non-display use for the operation of a Trading Platform and other non-display use, which is similar to exchanges such as BZX and EDGX,[64] while other exchanges maintain additional categories and in many cases charge multiple times for different types of non-display use or the operation of multiple Trading Platforms.[65]

The Exchange believes that it is reasonable to segment the fee for non-display use into these two categories. As noted above, the uses to which customers can put the MEMOIR Depth feed are numerous and varied, and the Exchange believes that charging separate fees for these separate categories of use is reasonable because it reflects the actual value the customer derives from the data, based upon how the customer makes use of the data.

The Exchange believes that the proposed fees for non-display use other than operation of a Trading Platform is reasonable. These fees are comparable to, and lower than, the fees charged by at least one other exchange of comparable size for a comparable data product,[66] and significantly less than the amounts charged by several other exchanges for comparable data products.[67] The Exchange believes that the proposed fees directly and appropriately reflect the significant value of using data on a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments. Further, in contrast to non-display use for operation of a Trading Platform, discussed below, the Exchange benefits from and wants to encourage other non-display use by market participants (including the fact that the Exchange receives orders resulting from algorithms and routers as well as more broadly beneficial uses such as risk management and compliance).

The Exchange also believes, regarding non-display use for operation of a Trading Platform, it is reasonable to charge a higher monthly fee than for other non-display use because such use of the Exchange's data is directly in competition with the Exchange and the Exchange should be permitted to recoup some of its lost trading revenue by charging for the data that makes such competition possible. The Exchange also believes that it is reasonable to charge the proposed fees for non-display use for operation of a Trading Platform because the proposed fees are comparable to, and lower than, the fees charged at least one other exchange of comparable size for a comparable data product,[68] and significantly less than the amounts charged by several other exchanges for comparable data products, which also charge per Trading Platform operated by a data subscriber subject to a cap in most cases, rather than charging per Firm, as proposed by the Exchange.[69]

The proposed Non-Display Usage fees for the Exchange Data Feeds are also reasonable because they take into account the extra value of receiving the data for Non-Display Usage that includes a rich set of information including top of book quotations, depth-of-book quotations, executions and other information. The Exchange believes that the proposed fees directly and appropriately reflect the significant value of using the MEMOIR Depth feed on a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments.[70]

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Exchange Data Feeds are reasonable.

The Proposed Fees Are Equitably Allocated

The Exchange believes the proposed fees for the Exchange Data Feeds are allocated fairly and equitably among the various categories of users of the feeds, and any differences among categories of users are justified and appropriate.

Overall. The Exchange believes that the proposed fees are equitably allocated because they will apply uniformly to all data recipients that choose to subscribe to the Exchange Data Feeds. Any subscriber or vendor that chooses to subscribe to one or more Exchange Data Feeds is subject to the same Fee Schedule, regardless of what type of business they operate, and the decision to subscribe to one or more Exchange Data Feeds is based on objective differences in usage of Exchange Data Feeds among different Firms, which are still ultimately in the control of any particular Firm. The Exchange believes the proposed pricing between Exchange Data Feeds is equitably allocated because it is based, in part, upon the amount of information contained in each data feed and the value of that information to market participants. The MEMOIR Top and Last Sale data feeds, as described above, can be utilized to trade on the Exchange but contain less information than that is available on the MEMOIR Depth feed (*i.e.,* even for a subscriber who takes both feeds, such feeds do not contain depth-of-book information). Thus, the Exchange believes it is an equitable allocation of fees for the products to be priced as proposed, with MEMOIR Last Sale having the lowest price, MEMOIR Top the next lowest price, and MEMOIR Depth the highest price (and more than MEMOIR Last Sale and MEMOIR Top combined).

Internal Distribution Fee. The Exchange believes the proposed monthly fees for Internal Distribution of the Exchange Data Feeds are equitably allocated because they would be charged on an equal basis to all data recipients that receive the Exchange Data Feeds for internal distribution, regardless of what type of business they operate.

External Distribution Fees. The Exchange believes the proposed monthly fees for External Distribution of the Exchange Data Feeds are equitably allocated because they would be

[64] *See* BZX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/;* EDGX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/edgx/.*

[65] *See supra* notes 26–27.

[66] *See* BZX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[67] *See* NYSE Proprietary Market Data Pricing list, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf;* Nasdaq Global Data Products pricing list, available at: *http://www.nasdaqtrader.com/TraderB.aspx?id=MDDPricingALLN.*.

[68] *See* BZX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[69] *See supra* notes 26–27.

[70] *See also* Exchange Act Release No. 69157, March 18, 2013, 78 FR 17946, 17949 (March 25, 2013) (SR–CTA/CQ–2013–01) (''[D]ata feeds have become more valuable, as recipients now use them to perform a far larger array of non-display functions. Some firms even base their business models on the incorporation of data feeds into black boxes and application programming interfaces that apply trading algorithms to the data, but that do not require widespread data access by the firm's employees. As a result, these firms pay little for data usage beyond access fees, yet their data access and usage is critical to their businesses.''

charged on an equal basis to all data recipients that receive the Exchange Data Feeds that choose to redistribute the feeds externally. The Exchange also believes that the proposed monthly fees for External Distribution are equitably allocated when compared to lower proposed fees for Internal Distribution because data recipients that are externally distributing Exchange Data Feeds are able to monetize such distribution and spread such costs amongst multiple third party data recipients, whereas the Internal Distribution fee is applicable to use by a single data recipient (and its affiliates).

User Fees. The Exchange believes that the fee structure differentiating Professional User fees from Non-Professional User fees for display use of the MEMOIR Depth feed is equitable. This structure has long been used by other exchanges and the SIPs to reduce the price of data to Non-Professional Users and make it more broadly available.[71] Offering the MEMOIR Depth feed to Non-Professional Users at a lower cost than Professional Users results in greater equity among data recipients, as Professional Users are categorized as such based on their employment and participation in financial markets, and thus, are compensated to participate in the markets. While Non-Professional Users too can receive significant financial benefits through their participation in the markets, the Exchange believes it is reasonable to charge more to those Users who are more directly engaged in the markets. The Exchange also believes it may be unreasonable to charge a Non-Professional User the same fee that it has proposed for Professional Users, as this fee would be higher than any other U.S. equities exchange charges to Non-Professional Users for receipt of a comparable data product. These User fees would be charged uniformly to all individuals that have access to the MEMOIR Depth feed based on the category of User. The Exchange also believes the proposed User fees for MEMOIR Top and MEMOIR Last Sale are equitable because the Exchange has proposed to charge Professional Users and Non-Professional Users the same low rate of $0.01 per month.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Usage fees are equitably allocated because they would require subscribers to pay fees only for the uses they actually make of the data. As noted above, non-display data can be used by data recipients for a wide variety of profit-generating purposes (including trading and order routing) as well as purposes that do not directly generate revenues (such as risk management and compliance) but nonetheless substantially reduce the recipient's costs by automating certain functions. The Exchange believes that it is equitable to charge non-display data subscribers that use data for purposes other than operation of a Trading Platform as proposed because all such subscribers would have the ability to use such data for as many non-display uses as they wish for one low fee. As noted above, this structure is comparable to that in place for the BZX Depth feed but several other exchanges charge multiple non-display fees to the same client to the extent they use a data feed in several different trading platforms or for several types of non-display use.[72]

The Exchange also believes, regarding non-display use for operation of a Trading Platform, it is equitable to charge a higher rate for each Firm operating a Trading Platform (as compared to other Non-Display Usage not by Trading Platforms) because such use of the data is directly in competition with the Exchange and the Exchange should be permitted to recoup some of its lost trading revenue by charging for the data that makes such competition possible. Further, in contrast to non-display use for operation of a Trading Platform, the Exchange benefits from and wants to encourage other non-display use by market participants (including the fact that the Exchange receives orders resulting from algorithms and routers as well as more broadly beneficial uses such as risk management and compliance). The Exchange believes that it is equitable to charge a single fee per Firm rather than multiple fees for a Firm that operates more than one Trading Platform because operators of Trading Platforms are many times viewed as a single competing venue or group, even if there are multiple liquidity pools operated by the same competitor.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Exchange Data Feeds are equitably allocated.

The Proposed Fees Are Not Unfairly Discriminatory

The Exchange believes the proposed fees for the Exchange Data Feeds are not unfairly discriminatory because any differences in the application of the fees are based on meaningful distinctions between customers, and those meaningful distinctions are not unfairly discriminatory between customers.

Overall. The Exchange believes that the proposed fees are not unfairly discriminatory because they would apply to all data recipients that choose to subscribe to the same Exchange Data Feed(s). Any vendor or subscriber that chooses to subscribe to the Exchange Data Feeds is subject to the same Fee Schedule, regardless of what type of business they operate. Because the proposed fees for MEMOIR Depth are higher, vendors and subscribers seeking lower cost options may instead choose to receive data from the SIPs or through the MEMOIR Top and/or MEMOIR Last Sale feed for a lower cost. Alternatively, vendors and subscribers can choose to pay for the MEMOIR Depth feed in order to receive data in a single feed with depth-of-book information if such information is valuable to such vendors or subscribers. The Exchange notes that vendors or subscribers can also choose to subscribe to a combination of data feeds for redundancy purposes or to use different feeds for different purposes. In sum, each vendor or subscriber has the ability to choose the best business solution for itself. The Exchange does not believe it is unfairly discriminatory to base pricing upon the amount of information contained in each data feed and the value of that information to market participants. As described above, the MEMOIR Top and Last Sale data feeds, can be utilized to trade on the Exchange but contain less information than that is available on the MEMOIR Depth feed (*i.e.,* even for a subscriber who takes both feeds, such feeds do not contain depth-of-book information). Thus, the Exchange believes it is not unfairly discriminatory for the products to be priced as proposed, with MEMOIR Last Sale having the lowest price, MEMOIR Top the next lowest price, and MEMOIR Depth the highest price (and more than MEMOIR Last Sale and MEMOIR Top combined).

Internal Distribution Fees. The Exchange believes the proposed monthly fees for Internal Distribution of the Exchange Data Feeds are not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the same Exchange Data Feed(s) for internal

[71] *See, e.g.,* Securities Exchange Act Release No. 59544 (March 9, 2009), 74 FR 11162 (March 16, 2009) (SR–NYSE–2008–131) (establishing the $15 Non-Professional User Fee (Per User) for NYSE OpenBook); Securities Exchange Act Release No. 20002, File No. S7–433 (July 22, 1983), 48 FR 34552 (July 29, 1983) (establishing Non-Professional fees for CTA data); NASDAQ BX Equity 7 Pricing Schedule, Section 123.

[72] *See supra,* notes 26–27.

distribution, regardless of what type of business they operate.

External Distribution Fees. The Exchange believes the proposed monthly fees for redistributing the Exchange Data Feeds are not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the same Exchange Data Feed(s) that choose to redistribute the feed(s) externally. The Exchange also believes that having higher monthly fees for External Distribution than Internal Distribution is not unfairly discriminatory because data recipients that are externally distributing Exchange Data Feeds are able to monetize such distribution and spread such costs amongst multiple third party data recipients, whereas the Internal Distribution fee is applicable to use by a single data recipient (and its affiliates).

User Fees. The Exchange believes that the fee structure differentiating Professional User fees from Non-Professional User fees for display use of the MEMOIR Depth feed is not unfairly discriminatory. This structure has long been used by other exchanges and the SIPs to reduce the price of data to Non-Professional Users and make it more broadly available.[73] Offering the Exchange Data Feeds to Non-Professional Users with the same data as is available to Professional Users results in greater equity among data recipients. These User fees would be charged uniformly to all individuals that have access to the Exchange Data Feeds based on the category of User. The Exchange also believes the proposed User fees for MEMOIR Top and MEMOIR Last Sale are not unfairly discriminatory because the Exchange has proposed to charge Professional Users and Non-Professional Users the same low rate of $0.01 per month.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Usage fees for the MEMOIR Depth feed are not unfairly discriminatory because they would require subscribers for non-display use to pay fees depending on their use of the data, either for operation of a Trading Platform or not, but would not impose multiple fees to the extent a Firm operates multiple Trading Platforms or has multiple different types of non-display use. As noted above, non-display data can be used by data recipients for a wide variety of profit-generating purposes as well as purposes that do not directly generate revenues but nonetheless substantially reduce the recipient's costs by automating certain functions. This segmented fee structure is not unfairly discriminatory because no subscriber of non-display data would be charged a fee for a category of use in which it did not actually engage.

The Exchange also believes that, regarding non-display use for operation of a Trading Platform, it is not unreasonably discriminatory to charge a higher fee for each Firm operating a Trading Platform (as compared to other Non-Display Usage not by Trading Platforms) because such use of the data is directly in competition with the Exchange and the Exchange should be permitted to recoup some of its lost trading revenue by charging for the data that makes such competition possible. The Exchange believes that it is not unreasonably discriminatory to charge a single fee for an operator of Trading Platforms that operates more than one Trading Platform because operators of Trading Platforms are many times viewed as a single competing venue or group, even if there a multiple liquidity pools operated by the same competitor. The Exchange again notes that certain competitors to the Exchange charge for non-display usage per Trading Platform,[74] in contrast to the Exchange's proposal. In turn, to the extent they subscribe to Exchange Data Feeds, these same competitors will benefit from the Exchange's pricing model to the extent they operate multiple Trading Platforms (as most do) by paying a single fee rather than paying for each Trading Platform that they operate that consumes Exchange Data Feeds.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Exchange Data Feeds are not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[75] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposed rule change would place certain market participants at the Exchange at a relative disadvantage compared to other market participants or affect the ability of such market participants to compete. Since the pricing for the Exchange Data Feeds was announced by the Exchange, the Exchange has received no official complaints from Members, non-Members, or third-parties that redistribute the Exchange Data Feeds, that the Exchange's fees or the proposed fees for Exchange Data Feeds would negatively impact their abilities to compete with other market participants or that they are placed at a disadvantage relative to others. The Exchange does not believe that the proposed fees for Exchange Data Feeds place certain market participants at a relative disadvantage to other market participants because, as noted above, the proposed fees are associated with usage of Exchange Data Feeds by each market participant based on the type of business they operate, and the decision to subscribe to one or more Exchange Data Feeds is based on objective differences in usage of Exchange Data Feeds among different Firms, which are still ultimately in the control of any particular Firm, and such fees do not impose a barrier to entry to smaller participants. Accordingly, the proposed fees for Exchange Data Feeds do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the proposed fees reflects the types of Exchange Data Feeds consumed by various market participants and their usage thereof.

As noted above, the current subscribers to the Exchange Data Feeds began changing their behavior in response to the imposition of fees as predicted in the Initial Proposal and as described herein. Following the date that fees for the Exchange Data Feeds were officially announced, fifteen (15) out of seventy-nine (79) subscribers, representing 19% of the subscribers to such data feeds, modified or canceled their subscriptions before the fees went into effect. In each instance, the subscriber told the Exchange that the reason for modifying or cancelling its subscription was the imminent imposition of fees. These modifications and cancellations are evidence that subscribing to the Exchange Data Feeds is discretionary, that each customer makes the decision whether to subscribe based on its own analysis of the benefits and costs to itself, and that customers can and do make those decisions quickly based on reactions to fee changes. Prior to the imposition of fees, four (4) customers (or 5% of market data subscribers) informed the Exchange that if the Exchange imposes the fees as proposed, such customers will limit their subscription the MEMOIR Top feed and/or the MEMOIR Last Sale feed, rather than the MEMOIR Depth feed, which is more expensive under the proposed fees. Notably, three (3) of these customers are active trading

[73] *See supra* note 71.

[74] *See supra* notes 26–27.

[75] 15 U.S.C. 78f(b)(8).

participants on the Exchange and have continued to participate on the Exchange without use of the Exchange's MEMOIR Depth feed. In addition, eleven (11) customers of the Exchange that were subscribed to receive Exchange Data Feeds have cancelled their subscriptions to such data feeds entirely (representing approximately 14% of market data subscribers). Five (5) of the eleven (11) customers that have cancelled all subscriptions to Exchange Data Feeds actively trade on the Exchange and have informed the Exchange that they will rely instead on SIP data to participate on the Exchange. This is clear evidence that the availability of these substitute products constrains the Exchange's ability to charge supra-competitive prices for the Exchange Data Feeds. The Exchange notes that the remaining customers that modified or cancelled their subscriptions to the Exchange Data Feeds (seven customers total) are not trading participants on the Exchange and likely subscribed to the Exchange Data Feeds initially because they were free but determined to cancel such subscriptions now that the Exchange is charging market data fees.

Inter-Market Competition

The Exchange does not believe the proposed fees place an undue burden on competition on other SROs that is not necessary or appropriate. In particular, market participants are not forced to subscribe to any of the Exchange Data Feeds, as described above. Additionally, other exchanges have similar market data fees in place for their participants, but with higher rates to connect.[76] The Exchange is also unaware of any assertion that the proposed fees for Exchange Data Feeds would somehow unduly impair its competition with other exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[77] and Rule 19b–4(f)(2)[78] thereunder.

[76] *See supra* notes 26–27; *see supra* note 29 and accompanying text.

[77] 15 U.S.C. 78s(b)(3)(A)(ii).

[78] 17 CFR 240.19b–4(f)(2).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MEMX–2022–19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MEMX–2022–19. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2022–19 and should be submitted on or before August 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[79]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17097 Filed 8–9–22; 8:45 am]

BILLING CODE 8011–01–P

[79] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34663; File No. 812–15342]

New Mountain Capital, L.L.C., et al.

August 4, 2022.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to amend a previous order granted by the Commission that permits certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

APPLICANTS: New Mountain Capital, L.L.C., New Mountain CLO 1, Ltd., New Mountain CLO 2, Ltd., New Mountain CLO 3, Ltd., New Mountain CLO 4, Ltd., New Mountain CLO 5, Ltd., New Mountain Credit CLO Advisers, L.L.C., New Mountain Finance Advisers BDC, L.L.C., New Mountain Finance Corporation, New Mountain Finance DB, L.L.C., New Mountain Finance Holdings, L.L.C., New Mountain Finance SBIC II, L.P., New Mountain Finance SBIC, L.P., New Mountain Finance Servicing, L.L.C., New Mountain Guardian II Master Fund–A, L.P., New Mountain Guardian II Master Fund–B, L.P., New Mountain Guardian III BDC, L.L.C., New Mountain Guardian III OEC, Inc., New Mountain Guardian

III SPV, L.L.C., New Mountain Guardian IV BDC, L.L.C., New Mountain Guardian Partners II, L.P., New Mountain Net Lease Corporation, New Mountain Net lease Partners II, L.P., New Mountain Net Lease Partners, L.P., New Mountain Partners VI, L.P., New Mountain Strategic Equity Fund I, L.P., New Mountain Strategic Equity Fund II, L.P., NMF Ancora Holdings, Inc., NMF HB, Inc., NMF OEC, Inc., NMF Permian Holdings L.L.C., NMF Pioneer, Inc., NMF QID NGL Holdings, Inc., NMF SLF I SPV, L.L.C., NMF SLF I, Inc., NMF TRM, L.L.C., and NMF YP Holdings, Inc.

FILING DATES: The application was filed on May 24, 2022, and amended on June 22, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on, August 29, 2022, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Robert A. Hamwee, Chief Executive Officer, New Mountain Finance Corporation, at *RHamwee@newmountaincapital.com,* and Steven B. Boehm, Esq., Payam Siadatpour, Esq., and Anne G. Oberndorf, Esq., Eversheds Sutherland (US) LLP, at *anneoberndorf@eversheds-sutherland.us.*

FOR FURTHER INFORMATION CONTACT: Kieran G. Brown, Senior Counsel, or Terri Jordan, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' first amended and restated application, dated June 22, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at, *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17113 Filed 8–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95425; File No. SR–NYSECHX–2022–06]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1, To Add Subparagraph (f)(4) Regarding Directed Orders to NYSE Chicago Rule 7.31

August 4, 2022.

I. Introduction

On April 20, 2022, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to introduce Directed Orders. The proposed rule change was published for comment in the **Federal Register** on May 3, 2022.[3] On June 16, 2022, the Commission extended to August 7, 2022, the time period in which to approve the proposal, disapprove the proposal, or institute proceedings to determine whether to approve or disapprove the proposal.[4] On July 28, 2022, the Exchange filed Amendment No. 1 to the proposed rule change with the Commission and submitted Amendment No. 1 for inclusion in the public comment file.[5] The Commission has received no comment letters on the proposed rule change. The Commission is publishing notice of the filing of Amendment No. 1 to solicit comment from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Self-Regulatory Organization's Description of the Proposal, as Modified by Amendment No. 1

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify Rule 7.31 (Orders and Modifiers) to add new subparagraph (f)(4) to provide for Directed Orders and to make other conforming changes to its Rules in connection with the addition of this new order type on the Exchange. The Directed Order, as further defined below, would be an order sent to the Exchange to be routed directly to an alternative trading system (''ATS'') specified by a Participant.[6]

The Exchange proposes to add Rule 7.31(f)(4), which would define a Directed Order as a Limit Order with instructions to route on arrival at its limit price to a specified ATS with which the Exchange maintains an electronic linkage. Proposed Rule 7.31(f)(4) would further provide that Directed Orders would be available for all securities eligible to trade on the Exchange. Proposed Rule 7.31(f)(4) would also provide that a Directed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 94837 (May 3, 2022), 87 FR 27681 (May 9, 2022) (SR–NYSECHX–2022–06) (''Notice'').

[4] *See* Securities Exchange Act Release No. 95119 (June 16, 2022), 87 FR 37538 (June 23, 2022).

[5] In Amendment No. 1, the Exchange: (i) represents that Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement; and (ii) updates the anticipated implementation date of the proposed rule change from the second quarter to the third quarter of 2022. *See* Letter from Martha Redding, Associate General Counsel, NYSE Chicago, Inc., to Secretary, Commission (July 28, 2022). Amendment No. 1 is available at *https://www.sec.gov/comments/sr-nysechx-2022-06/srnysechx202206-20135097-306077.pdf.*

[6] Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement.

Order would not be assigned a working time or interact with interest on the Exchange Book. The Exchange also proposes to provide in Rule 7.31(f)(4) that the ATS to which a Directed Order is routed would be responsible for validating whether the order is eligible to be accepted, and if such ATS determines to reject the order, the order would be cancelled.

Proposed Rule 7.31(f)(4)(A) would provide that a Directed Order must be designated for the Exchange's Core Trading Session, as defined in Rule 7.34(a)(2).[7]

Proposed Rule 7.31(f)(4)(A) would further provide that a Directed Order must be designated with a Time in Force modifier of IOC[8] or Day[9] and would be routed to the specified ATS with such modifier. The Exchange proposes that a Directed Order designated IOC would be traded in whole or in part on the ATS to which it is routed after receipt of the order, and any untraded quantity would be cancelled. The Exchange proposes that a Directed Order designated Day would expire at the end of the Core Trading Session on the day it is entered. Proposed Rule 7.31(f)(1)(A) would also provide that a Directed Order may not be designated with any other modifiers defined in Rule 7.31.

Proposed Rule 7.31(f)(4)(B) would provide that, during a trading halt or pause, an incoming Directed Order would be rejected.

Proposed Rule 7.31(f)(4)(C) would provide that a request to cancel a Directed Order designated Day would be routed to the ATS to which the order was routed.

The Exchange also proposes the following conforming changes to Rule 7.19 (Pre-Trade Risk Controls) and Article 17, Rule 5 (Brokerplex).

- The Exchange proposes to modify Rule 7.19(a)(5), which sets forth the definition of Gross Credit Risk Limit and currently provides that unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37(a)(1), and executed orders are included for purposes of calculating the Gross Credit Risk Limit. The Exchange proposes to modify Rule 7.19(a)(5) to specify that orders routed on arrival pursuant to Rule 7.31(f)(4) would also be included for purposes of the Gross Credit Risk Limit calculation.
- The Exchange proposes to modify Article 17, Rule 5, which describes the Brokerplex system used by Institutional Brokers (''IBs''). Specifically, the Exchange proposes to modify Rule 5(c)(1), which enumerates the order types and modifiers defined in Rule 7.31 that are not available via Brokerplex, to include Directed Orders because the order type will not be available to IBs.

The Exchange believes that the proposed rule change would facilitate additional trading opportunities by offering Participants the ability to designate orders submitted to the Exchange to be routed to an ATS of their choosing for execution. The Exchange believes the proposed change would encourage Participants to utilize the Exchange as a venue for order entry and further believes that the proposed change could create efficiencies for Participants by enabling them to send orders that they wish to route to an alternate destination through the Exchange, thereby enabling them to leverage order entry protocols and specifications already configured for their interactions with the Exchange. The Exchange notes that the Directed Order, as proposed, would operate similarly to the Primary Only Order already offered by the Exchange, which is an order that is routed directly to the primary listing market on arrival, without being assigned a working time or interacting with interest on the Exchange Book.[10] The Exchange also believes that the Directed Order would offer its Participants functionality akin to order types and routing options that currently exist on other equities exchanges.[11]

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update.[12] Subject to effectiveness of this proposed rule change, the Exchange anticipates that the proposed change will be implemented in the third quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934,[13] in general, and furthers the objectives of Section 6(b)(5),[14] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and

[7] Because the Exchange proposes that Directed Orders may only be designated for the Core Trading Session, the Exchange also proposes conforming changes to Rule 7.34 (Trading Sessions). Specifically, the Exchange proposes to modify Rule 7.34(c)(1)(E) to provide that Directed Orders designated for the Early Trading Session would be rejected and Rule 7.34(c)(3)(C) to provide that Directed Orders designated for the Late Trading Session would be rejected. The Exchange also proposes an additional change to correct a typographical error in Rule 7.34(c)(1), to update the reference to ''paragraphs (c)(1)(A)–(E)'' to ''paragraphs (c)(1)(A)–(F)'' to accurately reflect the number of subparagraphs under Rule 7.34(c)(1).

[8] *See* Rule 7.31(b)(2), which provides that a Limit Order may be designated with an Immediate-or-Cancel (''IOC'') modifier.

[9] *See* Rule 7.31(b)(1), which provides that orders may be designated with a Day modifier, and that an order to buy or sell designated Day, if not traded, will expire at the end of the designated session on the day on which it was entered.

[10] *See* Rule 7.31(f)(1). NYSE Chicago also offers variations of the Primary Only Order, including the Primary Only Until 9:45 Order, which is a Limit or Inside Limit Order that, on arrival and until 9:45 a.m. Eastern Time, routes to the primary listing market, and the Primary Only Until 3:55 Order, which is a Limit or Inside Limit Order entered on the Exchange until 3:55 p.m. Eastern Time, after which time the order is cancelled on the Exchange and routed to the primary listing market. *See* Rules 7.31(f)(2) and (f)(3). The Exchange's affiliated exchanges NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), and NYSE National, Inc. (''NYSE National'') (collectively, the ''Affiliated Exchanges'') also offer the Primary Only Order and variations thereof. *See* NYSE American Rules 7.31E(f)(1)–;(f)(3); NYSE Arca Rules 7.31–E(f)(1)–;(f)(3); NYSE National Rules 7.31(f)(1)–;(f)(3).

[11] *See, e.g.,* Nasdaq Stock Market LLC (''Nasdaq''), Equity 4, Equity Trading Rules, Rule 4758(a)(ix) (defining the Nasdaq Directed Order as an order designed to use a routing strategy under which the order is directed to an automated trading center other than Nasdaq, as directed by the entering party, without checking the Nasdaq Book); Cboe EDGX Exchange, Inc. (''EDGX'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGX system and is immediately routed by EDGX to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe EDGA Exchange, Inc. (''EDGA'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGA system and is immediately routed by EDGA to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe BZX Exchange, Inc. (''BZX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BZX system and be sent to a specified away trading center); Cboe BYX Exchange, Inc. (''BYX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BYX system and be sent to a specified away trading center). The Exchange also believes that the Directed Order would provide functionality similar to the C–LNK routing strategy formerly offered by EDGA, in which C–LNK orders bypassed EDGA's local book and routed directly to a specified Single Dealer Platform destination. *See* Securities Exchange Act Release No. 82904 (March 20, 2018), 83 FR 12995 (March 26, 2018) (SR–CboeEDGA–2018–004) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Expand an Offering Known a Cboe Connect To Provide Connectivity to Single-Dealer Platforms Connected to the Exchange's Network and To Propose a Per Share Executed Fee for Such Service).

[12] The Exchange will also provide information regarding the ATS(s) to which a Directed Order may be designated to route by Trader Update.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and promote just and equitable principles of trade because the Directed Order would offer Participants access to additional trading opportunities by permitting them to designate orders submitted to the Exchange to be routed directly to a specified ATS for execution. The Exchange further believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market by offering Participants the option to send orders that they wish to route to an alternate destination for execution through the Exchange, which would create efficiencies to the extent Participants are able to leverage existing protocols and specifications. Finally, the Exchange notes that the proposed functionality is not novel, as both the Exchange and other exchanges offer their members functionality whereby an exchange routes orders on behalf of a member to a specified trading center without such order interacting with the exchange's book.[15]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rules governing Directed Orders would promote competition because they would provide for an order type on the Exchange that would facilitate additional trading opportunities for market participants. The Exchange further believes that the proposed rules would allow it to offer Participants functionality similar to order types and routing options that exist on other equities exchanges, thereby enabling the Exchange to compete with such exchanges.[16]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Discussion and Commission Findings

After careful review of the proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[17] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[18] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and that the rules of a national securities exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission finds that the proposed rule change is reasonably designed to remove impediments to and perfect the mechanism of a free and open market and a national market system because it would provide Participants with additional trading opportunities by providing them with the option to designate orders to be routed by the Exchange directly to a specified ATS for execution. The use of Directed Orders would be voluntary, and the Exchange represents that it would not direct orders to any ATSs with which the Exchange has a financial relationship. The Commission also believes that the proposed rule change would not permit unfair discrimination among customers, brokers, or dealers because Directed Orders will be available to all Participants on an equal basis. Finally, the Commission believes that the proposed changes to Exchange Rule 7.19(a)(5) will ensure that Directed Orders are included in the calculation of Gross Credit Risk Limit.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSECHX–2022–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSECHX–2022–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSECHX–2022–06 and should be submitted on or before August 31, 2022.

[15] *See* notes 10 & 11, *supra.*

[16] *See* note 11, *supra.*

[17] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 15 U.S.C. 78f(b)(5).

V. Accelerated Approval of Amendment No. 1

As noted above,[19] in Amendment No. 1, as compared to the original proposal,[20] the Exchange: (i) represents that Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement; and (ii) updates the anticipated implementation date of the proposed rule change from the second quarter to the third quarter of 2022. The Commission finds that Amendment No. 1 to the proposal raises no novel regulatory issues, that it is reasonably designed to protect investors and the public interest, and that it is consistent with the requirements of the Act. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[21] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[22] that the proposed rule change (SR–NYSECHX–2022–06), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17101 Filed 8–9–22; 8:45 am]

BILLING CODE 8011–01–P

[19] *See supra* note 5.

[20] *See* Notice, *supra* note 3.

[21] 15 U.S.C. 78s(b)(2).

[22] 15 U.S.C. 78s(b)(2).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95422; File No. SR–CboeBZX–2022–006]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the WisdomTree Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

August 4, 2022.

On January 25, 2022, Cboe BZX Exchange, Inc. (''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the WisdomTree Bitcoin Trust under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on February 14, 2022.[3]

On March 18, 2022, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On May 13, 2022, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.[7] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act [8] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on February 14, 2022.[9] The 180th day after publication of the proposed rule change is August 13, 2022. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates October 12, 2022, as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR–CboeBZX–2022–006).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17098 Filed 8–9–22; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 94184 (Feb. 8, 2022), 87 FR 8318.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 94476, 87 FR 16800 (Mar. 24, 2022). The Commission designated May 15, 2022, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 94907, 87 FR 30546 (May 19, 2022).

[8] 15 U.S.C. 78s(b)(2).

[9] *See supra* note 3 and accompanying text.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95428; File No. SR–NYSEARCA–2022–25]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1, To Add Subparagraph (f)(4) Regarding Directed Orders to NYSE Arca Rule 7.31–E

August 4, 2022.

I. Introduction

On April 20, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to introduce Directed Orders. The proposed rule change was published for comment in the **Federal Register** on May 4, 2022.[3] On June 16, 2022, the Commission extended to August 8, 2022, the time period in which to approve the proposal, disapprove the proposal, or institute proceedings to determine whether to approve or disapprove the proposal.[4] On July 28, 2022, the Exchange filed Amendment No. 1 to the proposed rule change with the Commission and submitted Amendment No. 1 for inclusion in the public comment file.[5]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 94843 (May 4, 2022), 87 FR 28081 (May 10, 2022) (SR–NYSEARCA–2022–25) (''Notice'').

[4] *See* Securities Exchange Act Release No. 95116 (June 16, 2022), 87 FR 37543 (June 23, 2022).

[5] In Amendment No. 1, the Exchange: (i) represents that Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement; and (ii) updates the anticipated implementation date of the proposed rule change from the second quarter to the third quarter of 2022. *See* Letter from Martha Redding, Associate General Counsel, NYSE Arca, Inc., to Secretary, Commission

The Commission is publishing notice of the filing of Amendment No. 1 to solicit comment from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.[6]

II. Self-Regulatory Organization's Description of the Proposal, as Modified by Amendment No. 1

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify Rule 7.31–E (Orders and Modifiers) to add new subparagraph (f)(4) to provide for Directed Orders and to make other conforming changes to its Rules in connection with the addition of this new order type on the Exchange. The Directed Order, as further defined below, would be an order sent to the Exchange to be routed directly to an alternative trading system (''ATS'') specified by an ETP Holder.[7]

The Exchange proposes to add Rule 7.31–E(f)(4), which would define a Directed Order as a Limit Order with instructions to route on arrival at its limit price to a specified ATS with which the Exchange maintains an electronic linkage. Proposed Rule 7.31–E(f)(4) would further provide that Directed Orders would be available for all securities eligible to trade on the Exchange. Proposed Rule 7.31–E(f)(4) would also provide that a Directed Order would not be assigned a working time or interact with interest on the NYSE Arca Book. The Exchange also proposes to provide in Rule 7.31–E(f)(4) that the ATS to which a Directed Order is routed would be responsible for validating whether the order is eligible to be accepted, and if such ATS determines to reject the order, the order would be cancelled.

Proposed Rule 7.31–E(f)(4)(A) would provide that a Directed Order must be designated for the Exchange's Core Trading Session, as defined in Rule 7.34–E(a)(2).[8]

Proposed Rule 7.31–E(f)(4)(A) would further provide that a Directed Order must be designated with a Time in Force modifier of IOC[9] or Day[10] and would be routed to the specified ATS with such modifier. The Exchange proposes that a Directed Order designated IOC would be traded in whole or in part on the ATS to which it is routed after receipt of the order, and any untraded quantity would be cancelled. The Exchange proposes that a Directed Order designated Day would expire at the end of the Core Trading Session on the day it is entered. Proposed Rule 7.31–E(f)(1)(A) would also provide that a Directed Order may not be designated with any other modifiers defined in Rule 7.31–E.

Proposed Rule 7.31–E(f)(4)(B) would provide that a Directed Order in a security that is having its initial listing on the Exchange would be rejected if received before the IPO Auction concludes.

Proposed Rule 7.31–E(f)(4)(C) would provide that, during a trading halt or pause, an incoming Directed Order would be rejected.

Proposed Rule 7.31–E(f)(4)(D) would provide that a request to cancel a Directed Order designated Day would be routed to the ATS to which the order was routed.

The Exchange also proposes a conforming change to Rule 7.19–E (Pre-Trade Risk Controls). The Exchange proposes to modify Rule 7.19–E(a)(5), which sets forth the definition of Gross Credit Risk Limit and currently provides that unexecuted orders in the NYSE Arca Book, orders routed on arrival pursuant to Rule 7.37–E(a)(1), and executed orders are included for purposes of calculating the Gross Credit Risk Limit. The Exchange proposes to modify Rule 7.19–E(a)(5) to specify that orders routed on arrival pursuant to Rule 7.31–E(f)(4) would also be included for purposes of the Gross Credit Risk Limit calculation.

The Exchange believes that the proposed rule change would facilitate additional trading opportunities by offering ETP Holders the ability to designate orders submitted to the Exchange to be routed to an ATS of their choosing for execution. The Exchange believes the proposed change would encourage ETP Holders to utilize the Exchange as a venue for order entry and further believes that the proposed change could create efficiencies for ETP Holders by enabling them to send orders that they wish to route to an alternate destination through the Exchange, thereby enabling them to leverage order entry protocols and specifications already configured for their interactions with the Exchange. The Exchange notes that the Directed Order, as proposed, would operate similarly to the Primary Only Order already offered by the Exchange, which is an order that is routed directly to the primary listing market on arrival, without being assigned a working time or interacting with interest on the NYSE Arca Book.[11] The Exchange also believes that the Directed Order would offer ETP Holders functionality akin to order types and routing options that currently exist on other equities exchanges.[12]

(July 28, 2022). Amendment No. 1 is available at *https://www.sec.gov/comments/sr-nysearca-2022-25/srnysearca202225-20135099-306079.pdf.*

[6] The Commission received one comment letter that is not germane to the proposal. *See https://www.sec.gov/comments/sr-nysearca-2022-25/srnysearca202225-289416.htm.*

[7] Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement.

[8] Because the Exchange proposes that Directed Orders may only be designated for the Core Trading Session, the Exchange also proposes conforming changes to Rule 7.34–E (Trading Sessions). Specifically, the Exchange proposes to modify Rule 7.34–E(c)(1)(E) to provide that Directed Orders designated for the Early Trading Session would be rejected and Rule 7.34–E(c)(3)(C) to provide that Directed Orders designated for the Late Trading Session would be rejected.

[9] *See* Rule 7.31–E(b)(2), which provides that a Limit Order may be designated with an Immediate-or-Cancel (''IOC'') modifier.

[10] *See* Rule 7.31–E(b)(1), which provides that orders may be designated with a Day modifier, and that an order to buy or sell designated Day, if not traded, will expire at the end of the designated session on the day on which it was entered.

[11] *See* Rule 7.31–E(f)(1). NYSE Arca also offers variations of the Primary Only Order, including the Primary Only Until 9:45 Order, which is a Limit or Inside Limit Order that, on arrival and until 9:45 a.m. Eastern Time, routes to the primary listing market, and the Primary Only Until 3:55 Order, which is a Limit or Inside Limit Order entered on the Exchange until 3:55 p.m. Eastern Time, after which time the order is cancelled on the Exchange and routed to the primary listing market. *See* Rules 7.31–E(f)(2) and (f)(3). The Exchange's affiliated exchanges NYSE American LLC (''NYSE American''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'') (collectively, the ''Affiliated Exchanges'') also offer the Primary Only Order and variations thereof. *See* NYSE American Rules 7.31E(f)(1)—(f)(3); NYSE Chicago Rules 7.31(f)(1)—(f)(3); NYSE National Rules 7.31(f)(1)—(f)(3).

[12] *See, e.g.,* Nasdaq Stock Market LLC (''Nasdaq''), Equity 4, Equity Trading Rules, Rule 4758(a)(ix) (defining the Nasdaq Directed Order as an order designed to use a routing strategy under which the order is directed to an automated trading center other than Nasdaq, as directed by the entering party, without checking the Nasdaq Book); Cboe EDGX Exchange, Inc. (''EDGX'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGX system and is immediately routed by EDGX to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe EDGA Exchange, Inc. (''EDGA'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGA system

Continued

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update.[13] Subject to effectiveness of this proposed rule change, the Exchange anticipates that the proposed change will be implemented in the third quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934,[14] in general, and furthers the objectives of Section 6(b)(5),[15] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and promote just and equitable principles of trade because the Directed Order would offer ETP Holders access to additional trading opportunities by permitting them to designate orders submitted to the Exchange to be routed directly to a specified ATS for execution. The Exchange further believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market by offering ETP Holders the option to send orders that they wish to route to an alternate destination for execution through the Exchange, which would create efficiencies to the extent ETP Holders are able to leverage existing protocols and specifications. Finally, the Exchange notes that the proposed functionality is not novel, as both the Exchange and other exchanges offer their members functionality whereby an exchange routes orders on behalf of a member to a specified trading center without such order interacting with the exchange's book.[16]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rules governing Directed Orders would promote competition because they would provide for an order type on the Exchange that would facilitate additional trading opportunities for market participants. The Exchange further believes that the proposed rules would allow it to offer ETP Holders functionality similar to order types and routing options that exist on other equities exchanges, thereby enabling the Exchange to compete with such exchanges.[17]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Discussion and Commission Findings

After careful review of the proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[18] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[19] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and that the rules of a national securities exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission finds that the proposed rule change is reasonably designed to remove impediments to and perfect the mechanism of a free and open market and a national market system because it would provide ETP Holders with additional trading opportunities by providing them with the option to designate orders to be routed by the Exchange directly to a specified ATS for execution. The use of Directed Orders would be voluntary, and the Exchange represents that it would not direct orders to any ATSs with which the Exchange has a financial relationship. The Commission also believes that the proposed rule change would not permit unfair discrimination among customers, brokers, or dealers because Directed Orders will be available to all ETP Holders on an equal basis. Finally, the Commission believes that the proposed changes to Exchange Rule 7.19–E(a)(5) will ensure that Directed Orders are included in the calculation of Gross Credit Risk Limit.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2022–25 on the subject line.

and is immediately routed by EDGA to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe BZX Exchange, Inc. (''BZX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BZX system and be sent to a specified away trading center); Cboe BYX Exchange, Inc. (''BYX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BYX system and be sent to a specified away trading center). The Exchange also believes that the Directed Order would provide functionality similar to the C–LNK routing strategy formerly offered by EDGA, in which C–LNK orders bypassed EDGA's local book and routed directly to a specified Single Dealer Platform destination. *See* Securities Exchange Act Release No. 82904 (March 20, 2018), 83 FR 12995 (March 26, 2018) (SR–CboeEDGA–2018–004) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Expand an Offering Known a Cboe Connect To Provide Connectivity to Single-Dealer Platforms Connected to the Exchange's Network and To Propose a Per Share Executed Fee for Such Service).

[13] The Exchange will also provide information regarding the ATS(s) to which a Directed Order may be designated to route by Trader Update.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] *See* notes 11 & 12, *supra.*

[17] *See* note 12, *supra.*

[18] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 15 U.S.C. 78f(b)(5).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2022–25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2022–25 and should be submitted on or before August 31, 2022.

V. Accelerated Approval of Amendment No. 1

As noted above,[20] in Amendment No. 1, as compared to the original proposal,[21] the Exchange: (i) represents that Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement; and (ii) updates the anticipated implementation date of the proposed rule change from the second quarter to the third quarter of 2022. The Commission finds that Amendment No. 1 to the proposal raises no novel regulatory issues, that it is reasonably designed to protect investors and the public interest, and that it is consistent with the requirements of the Act. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[22] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[23] that the proposed rule change (SR–NYSEARCA–2022–25), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17103 Filed 8–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95423; File No. SR–NYSE–2022–20]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1, To Add Subparagraph (f)(1) Regarding Directed Orders to NYSE Rule 7.31

August 4, 2022.

I. Introduction

On April 20, 2022, New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to introduce Directed Orders. The proposed rule change was published for comment in the **Federal Register** on May 3, 2022.[3] On June 16, 2022, the Commission extended to August 7, 2022, the time period in which to approve the proposal, disapprove the proposal, or institute proceedings to determine whether to approve or disapprove the proposal.[4] On July 28, 2022, the Exchange filed Amendment No. 1 to the proposed rule change with the Commission and submitted Amendment No. 1 for inclusion in the public comment file.[5] The Commission is publishing notice of the filing of Amendment No. 1 to solicit comment from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.[6]

II. Self-Regulatory Organization's Description of the Proposal, as Modified by Amendment No. 1

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify Rule 7.31 (Orders and Modifiers) to designate subparagraph (f) as describing orders with specific routing instructions and to add new subparagraph (f)(1) to provide for Directed Orders. The Exchange also proposes to make other conforming changes to its Rules in connection with the addition of this new order type on the Exchange. The Directed Order, as further defined below, would be an order sent to the Exchange to be routed directly to an alternative trading system (''ATS'') specified by a member organization.[7]

The Exchange proposes to rename Rule 7.31(f), which is currently designated as Reserved, to ''Orders with Specific Routing Instructions.'' The Exchange also proposes to add Rule 7.31(f)(1), which would define a Directed Order as a Limit Order with instructions to route on arrival at its

[20] *See supra* note 5.

[21] *See* Notice, *supra* note 3.

[22] 15 U.S.C. 78s(b)(2).

[23] 15 U.S.C. 78s(b)(2).

[24] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 94839 (May 3, 2022), 87 FR 27679 (May 9, 2022) (SR–NYSE–2022–20) (''Notice'').

[4] *See* Securities Exchange Act Release No. 95118 (June 16, 2022), 87 FR 37539 (June 23, 3022).

[5] In Amendment No. 1, the Exchange: (i) represents that Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement; and (ii) updates the anticipated implementation date of the proposed rule change from the second quarter to the third quarter of 2022. *See* Letter from Martha Redding, Associate General Counsel, NYSE LLC, to Secretary, Commission (July 28, 2022). Amendment No. 1 is available at *https://www.sec.gov/comments/sr-nyse-2022-20/srnyse202220-20135101-306081.pdf.*

[6] The Commission received one comment letter that is not germane to the proposal. *See https://www.sec.gov/comments/sr-nyse-2022-20/srnyse202220-289428.htm.*

[7] Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement.

limit price to a specified ATS with which the Exchange maintains an electronic linkage. Proposed Rule 7.31(f)(1) would further provide that Directed Orders would be available for all securities eligible to trade on the Exchange. Proposed Rule 7.31(f)(1) would also provide that a Directed Order would not be assigned a working time or interact with interest on the Exchange Book. The Exchange also proposes to provide in Rule 7.31(f)(1) that the ATS to which a Directed Order is routed would be responsible for validating whether the order is eligible to be accepted, and if such ATS determines to reject the order, the order would be cancelled.

Proposed Rule 7.31(f)(1)(A) would provide that a Directed Order must be designated for the Exchange's Core Trading Session, as defined in Rule 7.34(a)(2).[8]

Proposed Rule 7.31(f)(1)(A) would further provide that a Directed Order must be designated with a Time in Force modifier of IOC[9] or Day[10] and would be routed to the specified ATS with such modifier. The Exchange proposes that a Directed Order designated IOC would be traded in whole or in part on the ATS to which it is routed after receipt of the order, and any untraded quantity would be cancelled. The Exchange proposes that a Directed Order designated Day would expire at the end of the Core Trading Session on the day it is entered. Proposed Rule 7.31(f)(1)(A) would also provide that a Directed Order may not be designated with any other modifiers defined in Rule 7.31.

Proposed Rule 7.31(f)(1)(B) would provide that a Directed Order in a security to be opened in an initial public offering (''IPO'') or a Direct Listing would be rejected if received before the IPO Auction or Direct Listing Auction concludes.

Proposed Rule 7.31(f)(1)(C) would provide that, during a trading halt or pause, an incoming Directed Order would be rejected.

Proposed Rule 7.31(f)(1)(D) would provide that a request to cancel a Directed Order designated Day would be routed to the ATS to which the order was routed.

The Exchange also proposes the following conforming changes to Rule 7.19 (Pre-Trade Risk Controls) and Rule 104 (Dealings and Responsibilities of DMMs):

- The Exchange proposes to modify Rule 7.19(a)(5), which sets forth the definition of Gross Credit Risk Limit and currently provides that unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37(a)(1), and executed orders are included for purposes of calculating the Gross Credit Risk Limit. The Exchange proposes to modify Rule 7.19(a)(5) to specify that orders routed on arrival pursuant to Rule 7.31(f)(1) would also be included for purposes of the Gross Credit Risk Limit calculation.
- The Exchange proposes to modify Rule 104(b)(6), which specifies the orders and modifiers that DMM units are not permitted to enter. The Exchange proposes to add Directed Orders to Rule 104(b)(6) as an order type that DMM units may not enter.

The Exchange believes that the proposed rule change would facilitate additional trading opportunities by offering member organizations the ability to designate orders submitted to the Exchange to be routed to an ATS of their choosing for execution. The Exchange believes the proposed change would encourage member organizations to utilize the Exchange as a venue for order entry and further believes that the proposed change could create efficiencies for member organizations by enabling them to send orders that they wish to route to an alternate destination through the Exchange, thereby enabling them to leverage order entry protocols and specifications already configured for their interactions with the Exchange. The Exchange notes that the Directed Order, as proposed, would operate similarly to the Primary Only Order already offered by NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'') (collectively, the ''Affiliated Exchanges''). On the Affiliated Exchanges, a Primary Only Order is an order that is routed directly to the primary listing market on arrival, without being assigned a working time or interacting with interest on the order book of the exchange to which it was submitted.[11] The Exchange also believes that the Directed Order would offer member organizations functionality akin to order types and routing options that currently exist on other equities exchanges.[12]

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update.[13] Subject to effectiveness of this proposed rule change, the Exchange anticipates that the proposed change will be implemented in the third quarter of 2022.

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[8] Because the Exchange proposes that Directed Orders may only be designated for the Core Trading Session, the Exchange also proposes conforming changes to Rule 7.34 (Trading Sessions). Specifically, the Exchange proposes to add Rule 7.34(c)(1)(E) to provide that Directed Orders designated for the Early Trading Session would be rejected. The Exchange also proposes to update Rule 7.34(c)(1) to refer to ''paragraphs (c)(1)(A)–(E)'' to reflect the addition of subparagraph (E).

[9] *See* Rule 7.31(b)(2), which provides that a Limit Order may be designated with an Immediate-or-Cancel (''IOC'') modifier.

[10] *See* Rule 7.31(b)(1), which provides that orders may be designated with a Day modifier, and that an order to buy or sell designated Day, if not traded, will expire at the end of the designated session on the day on which it was entered.

[11] *See* NYSE American Rule 7.31E(f)(1); NYSE Arca Rule 7.31–E(f)(1); NYSE Chicago Rule 7.31(f)(1); NYSE National Rule 7.31(f)(1). The Affiliated Exchanges also offer variations of the Primary Only Order, including the Primary Only Until 9:45 Order, which is a Limit or Inside Limit Order that, on arrival and until 9:45 a.m. Eastern Time, routes to the primary listing market, and the Primary Only Until 3:55 Order, which is a Limit or Inside Limit Order entered on the Exchange until 3:55 p.m. Eastern Time, after which time the order is cancelled on the Exchange and routed to the primary listing market. *See* NYSE American Rules 7.31E(f)(2) and (f)(3); NYSE Arca Rules 7.31–E(f)(2) and (f)(3); NYSE Chicago Rules 7.31(f)(2) and (f)(3); NYSE National Rules 7.31(f)(2) and (f)(3).

[12] *See, e.g.,* Nasdaq Stock Market LLC (''Nasdaq''), Equity 4, Equity Trading Rules, Rule 4758(a)(ix) (defining the Nasdaq Directed Order as an order designed to use a routing strategy under which the order is directed to an automated trading center other than Nasdaq, as directed by the entering party, without checking the Nasdaq Book); Cboe EDGX Exchange, Inc. (''EDGX'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGX system and is immediately routed by EDGX to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe EDGA Exchange, Inc. (''EDGA'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGA system and is immediately routed by EDGA to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe BZX Exchange, Inc. (''BZX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BZX system and be sent to a specified away trading center); Cboe BYX Exchange, Inc. (''BYX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BYX system and be sent to a specified away trading center). The Exchange also believes that the Directed Order would provide functionality similar to the C–LNK routing strategy formerly offered by EDGA, in which C–LNK orders bypassed EDGA's local book and routed directly to a specified Single Dealer Platform destination. *See* Securities Exchange Act Release No. 82904 (March 20, 2018), 83 FR 12995 (March 26, 2018) (SR–CboeEDGA–2018–004) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Expand an Offering Known a Cboe Connect To Provide Connectivity to Single-Dealer Platforms Connected to the Exchange's Network and To Propose a Per Share Executed Fee for Such Service).

[13] The Exchange will also provide information regarding the ATS(s) to which a Directed Order may be designated to route by Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934,[14] in general, and furthers the objectives of Section 6(b)(5),[15] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and promote just and equitable principles of trade because the Directed Order would offer member organizations access to additional trading opportunities by permitting them to designate orders submitted to the Exchange to be routed directly to a specified ATS for execution. The Exchange further believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market by offering member organizations the option to send orders that they wish to route to an alternate destination for execution through the Exchange, which would create efficiencies to the extent member organizations are able to leverage existing protocols and specifications. Finally, the Exchange notes that the proposed functionality is not novel as the Affiliated Exchanges and other exchanges offer their members functionality whereby an exchange routes orders on behalf of a member to a specified trading center without such order interacting with the Exchange's book.[16]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rules governing Directed Orders would promote competition because they would provide for an order type on the Exchange that would facilitate additional trading opportunities for market participants. The Exchange further believes that the proposed rules would allow it to offer its member organizations functionality similar to order types and routing options that exist on other equities exchanges, thereby enabling the Exchange to compete with such exchanges.[17]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Discussion and Commission Findings

After careful review of the proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[18] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[19] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and that the rules of a national securities exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission finds that the proposed rule change is reasonably designed to remove impediments to and perfect the mechanism of a free and open market and a national market system because it would provide exchange members with additional trading opportunities by providing them with the option to designate orders to be routed by the Exchange directly to a specified ATS for execution. The use of Directed Orders would be voluntary, and the Exchange represents that it would not direct orders to any ATSs with which the Exchange has a financial relationship. The Commission also believes that the proposed rule change would not permit unfair discrimination among customers, brokers, or dealers because Directed Orders will be available to all Exchange members on an equal basis. Finally, the Commission believes that the proposed changes to Exchange Rule 7.19(a)(5) will ensure that Directed Orders are included in the calculation of Gross Credit Risk Limit.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2022–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2022–20. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] *See* notes 11 & 12, *supra.*

[17] *See* note 12, *supra.*

[18] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 15 U.S.C. 78f(b)(5).

to make available publicly. All submissions should refer to File Number SR–NYSE–2022–20 and should be submitted on or before August 31, 2022.

V. Accelerated Approval of Amendment No. 1

As noted above,[20] in Amendment No. 1, as compared to the original proposal,[21] the Exchange: (i) represents that Directed Orders will not be routed to an ATS with which the Exchange has a financial arrangement; and (ii) updates the anticipated implementation date of the proposed rule change from the second quarter to the third quarter of 2022. The Commission finds that Amendment No. 1 to the proposal raises no novel regulatory issues, that it is reasonably designed to protect investors and the public interest, and that it is consistent with the requirements of the Act. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[22] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[23] that the proposed rule change (SR–NYSE–2022–20), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17099 Filed 8–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34664; File No. 812–15350]

Runway Growth Finance Corp., et al.

August 4, 2022.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to amend a previous order granted by the Commission that permits certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

APPLICANTS: Runway Growth Finance Corp., Runway Growth Finance L.P., Runway Growth Capital LLC, RWAY IP Holdings LLC and Runway Growth Finance Opportunities Fund I LP.

FILING DATES: The application was filed on June 15, 2022 and amended on July 29, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on August 29, 2022, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Thomas B. Raterman at *tr@runwaygrowth.com.* Steven B. Boehm, Esq. and Anne G. Oberndorf, Esq., Eversheds Sutherland (US) LLP, at *anneoberndorf@eversheds-sutherland.us.*

FOR FURTHER INFORMATION CONTACT: Bruce R. MacNeil, Senior Counsel, or Kaitlin C. Bottock, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' first amended and restated application, dated July 29, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at, at *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17118 Filed 8–9–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95430; File No. SR–BOX–2022–24)

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Options Market LLC Facility To Establish Section IV.D.2 (''Strategy QCC Transactions'')

August 4, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2022, BOX Exchange LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the Fee Schedule to amend the Fee Schedule for trading on BOX to establish Section IV.D.2 (''Strategy QCC Transactions'') on the BOX Options Market LLC (''BOX'') options facility. While changes to the fee schedule

[20] *See supra* note 5.

[21] *See* Notice, *supra* note 3.

[22] 15 U.S.C. 78s(b)(2).

[23] 15 U.S.C. 78s(b)(2).

[24] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

pursuant to this proposal will be effective upon filing, the changes will become operative on August 1, 2022. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *http://boxexchange.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule for trading on BOX to establish Section IV.D.2 (''Strategy QCC Transactions'').

Currently, the transaction fees for Qualified Contingent Cross (''QCC'') Orders, including strategy QCC Orders, are detailed in Section IV.D. in the Fee Schedule. Broker Dealer and Market Maker QCC transactions are assessed $0.17 per contract for both the Agency Order and the Contra Order. Public Customers and Professional Customers are assessed $0.00 for both the Agency Order and the Contra Order and are eligible for a rebate if at least one side of the QCC transaction is a Broker Dealer or Market Maker.[5]

To further incentivize Participants to execute strategy[6] QCC transactions on BOX, the Exchange now proposes to establish Section IV.D.2 that will detail the fees assessed for these transactions.[7] Specifically, the Exchange proposes to assess no fees for strategy QCC transactions which are comprised of an originating order to buy or sell at least 1,000 contracts, or 10,000 mini-option contracts, that is identified as being part of a qualified contingent trade, as that term is defined in IM–7110–2 below, coupled with a contra-side order or orders totaling an equal number of contracts. IM–7110–2 provides a ''qualified contingent trade'' is a transaction consisting of two or more component orders, executed as agent or principal, where: (1) At least one component is an NMS Stock, as defined in Rule 600 of Regulation NMS under the Exchange Act; (2) all components are effected with a product or price contingency that either has been agreed to by all the respective counterparties or arranged for by a broker dealer as principal or agent; (3) the execution of one component is contingent upon the execution of all other components at or near the same time; (4) the specific relationship between the component orders (*e.g.,* the spread between the prices of the component orders) is determined by the time the contingent order is placed; (5) the component orders bear a derivative relationship to one another, represent different classes of shares of the same issuer, or involve the securities of participants in mergers or with intentions to merge that have been announced or cancelled; and (6) the transaction is fully hedged (without regard to any prior existing position) as a result of other components of the contingent trade.[8] Because these transactions will not be assessed a fee, the Exchange proposes that strategy QCC transactions will not be eligible for a QCC Rebate and will not count toward QCC Agency Order volume detailed in Section IV.D.1. The Exchange notes that strategy QCC transactions will continue to count toward Market Maker and Public Customer monthly executed volume on BOX detailed in Section IV.A.1 of the BOX Fee Schedule but will not be eligible for the QCC Rebate in Section IV.D.1 and will not be counted towards the QCC Rebate Tiers.

The proposed change is designed to compete with open outcry fee caps for strategy orders.[9] The Exchange believes that Participants may choose to execute strategy orders that would qualify as strategy QCC Orders either in open outcry or as electronic QCC transactions depending on convenience, fees, and access to Floor Brokers. The Exchange believes that Participants are otherwise indifferent to whether a strategy order is executed in open outcry or electronically. Therefore, the proposed change is designed to further incentivize certain Participants to direct strategy order volume to BOX's electronic QCC mechanism rather than to another exchange's trading floor.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5) of the Act,[10] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other

[5] *See* BOX Fee Schedule, Section IV.D, ''Qualified Contingent Cross (''QCC'') Transactions.''

[6] Strategy orders are defined as one of the following: A ''short stock interest strategy'' is defined as a transaction done to achieve a short stock interest arbitrage involving the purchase, sale, and exercise of in-the-money options of the same class. A ''long stock interest strategy'' is defined as a transaction done to achieve long stock involving the purchase, sale, and exercise of in-the-money options of the same class. A ''merger strategy'' is defined as transactions done to achieve a merger arbitrage involving the purchase, sale and exercise of options of the same class and expiration date, each executed prior to the date on which shareholders of record are required to elect their respective form of consideration, *i.e.,* cash or stock. A ''reversal strategy'' is established by combining a short security position with a short put and a long call position that shares the same strike and expiration. A ''conversion strategy'' is established by combining a long position in the underlying security with a long put and a short call position that shares the same strike and expiration. A ''jelly roll strategy'' is created by entering into two separate positions simultaneously. One position involves buying a put and selling a call with the same strike price and expiration. The second position involves selling a put and buying a call, with the same strike price, but with a different expiration from the first position. A ''box spread strategy'' is a strategy that synthesizes long and short stock positions to create a profit. Specifically, a long call and short put at one strike is combined with a short call and long put at a different strike to create synthetic long and synthetic short stock positions, respectively. A ''dividend strategy'' is defined as a transaction done to achieve a dividend arbitrage involving the purchase, sale and exercise of in-the-money options of the same class, executed the first business day prior to the date on which the underlying stock goes ex-dividend. *See* BOX Fee Schedule, notes 29 and 35.

[7] The Exchange notes that Public Customers and Professional Customers are not charged a fee for QCC Orders. Therefore, the Exchange believes that Public Customers and Professional Customers will not be as incentivized as other Participants by the proposed fees.

[8] BOX Rule 7110(c)(6).

[9] The Exchange's proposal to not assess fees on strategy QCC transactions is similar to Cboe Exchange, Inc. (''CBOE''), which caps open outcry strategy transactions at $0.00. *See* CBOE Fee Schedule, ''QCC Rate Table''; footnote 13. CBOE's fee cap applies to open outcry strategy transactions. Although, the proposed strategy QCC Orders are executed electronically, the Exchange believes that executing strategy orders as QCC orders is an alternative for trading strategy orders in open outcry. As such, the proposed change will allow BOX to compete with other exchanges who offer strategy orders at no cost. BOX notes that other exchanges offer fee caps on open outcry strategy transactions as well. *See generally* NYSE American Options Fee Schedule, Section I(J), ''Options Transaction Fees and Credits'' (Strategy transactions in open outcry and QCC reversal and conversion strategies are capped at $1,000 on the same trading day. The cap is reduced to $200 per trading day for ATP Holders that trade at least 25,000 billable contract sides in qualifying strategy executions) *and* Nasdaq PHLX LLC Rules Options 7, Section 4 (reversal and conversion strategies capped at $200 per day; merger, short stock interest, and box spread strategies capped at $1,000 per day if more than one class of options or $700 per day if in a single class of options; dividend strategies capped at $1,100 per day; all strategies capped at $65,000 per month per member organization).

[10] 15 U.S.C. 78f(b)(4) and (5).

charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange notes that it operates in a highly competitive environment. Indeed, there are currently 16 registered options exchanges that trade options. Based on publicly available information, no single options exchange has more than 16% of the market share and currently the Exchange represents only approximately 6% of the market share.[11] The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Particularly, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12] As stated above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed fee changes reflect a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange.

The Exchange believes the proposed change is reasonable, equitable, and not unfairly discriminatory as there are other exchanges with similar fees or fee caps for strategy orders [13] and the proposed fees are uniformly applicable to all Participants. The Exchange also believes the proposed change would further incentivize certain Participants to execute strategy QCC Orders on BOX and may encourage Participants to aggregate all types of strategy orders (*i.e.* QCC Orders and Qualified Open Outcry (''QOO'') Orders) at BOX as a primary execution venue. The Exchange believes that Participants may consolidate different order types for execution on a single exchange because it increases the volume counted towards volume-based fee incentives, in particular, the Tiered Volume Rebate for Non-Auction Transactions in Section IV.A.1., of BOX's Fee Schedule, which provides Participants with incentives to achieve certain volume thresholds on BOX. To the extent that the proposed change attracts more strategy orders to BOX, some of which may be executed as QCC Orders and others as QOO Orders, this increased order flow may make BOX a more competitive venue for order execution.

The Exchange also believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow. The Exchange believes the proposed change is a reasonable attempt to further incentivize certain Participants to execute strategy orders on BOX and in turn to increase the depth of its market to the benefit of all market participants. The Exchange also notes that Participants may avail themselves to the proposed strategy order pricing or they can opt for similar offerings at several other exchanges.[14]

The Exchange believes that not allowing strategy QCC transactions to be eligible for a rebate is reasonable, equitable and not unfairly discriminatory because, as proposed, a fee is not assessed for these transactions. As such, the Exchange believes that Participants do not require additional incentives to execute these transactions on BOX. The QCC Rebate and Tiers detailed in Section IV.D.1 of the BOX Fee Schedule were designed to reduce the QCC fees assessed to Participants in Section IV.D. The proposal discussed herein is to assess no fee on strategy QCC Orders therefore there is no fee to reduce. Further, the Exchange believes that it is reasonable, equitable and not unfairly discriminatory to not count strategy QCC Order volume towards QCC Tiers because the Exchange does not believe that Participants need additional incentives to transact strategy QCC Orders on BOX.

The Exchange believes that it is reasonable, equitable and not unfairly discriminatory to continue to count strategy QCC transactions toward the Tiered Volume Rebate for Non-Auction Transactions in Section IV.A.1., which provides Participants with incentives to achieve certain volume thresholds on BOX. These volume tiers are designed to reflect a reasonable and competitive pricing structure, to incentivize market participants to direct their order flow to BOX, and to enhance market quality. The Exchange believes that allowing strategy QCC orders to count toward customer volume tiers is equitable and not unfairly discriminatory because BOX has historically aimed to improve markets for investors and develop various features within the market structure for public customer benefit. The Exchange believes further that allowing strategy QCC orders to count toward Market Maker volume tiers is equitable and not unfairly discriminatory because of the significant contribution to overall market quality that Market Makers provide. Specifically, Market Makers provide higher volumes of liquidity which ultimately benefits all Participants trading on BOX.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The proposed change is designed to attract additional order flow to BOX. The Exchange believes that the proposed change could further incentivize certain market participants to direct their strategy QCC Orders to BOX. As noted herein, the proposed strategy QCC Order fees would be applicable to all similarly situated market participants, and, as such, the proposed change would not impose a disparate burden on competition among Participants on BOX.

Further, the Exchange also does not believe that the proposed fees will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the Act because, as noted above, competing options exchanges currently have similar fees in place in connection with strategy orders.[15] Because competitors are free to modify their own fees or fee caps in response to competing exchanges, BOX believes that the degree to which changes in this market may impose any burden on competition is limited. Further, the Exchange believes that the proposed change could promote competition between BOX and other execution venues, including those that currently offer similar strategy order fees or fee caps. Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the

[11] *See* Cboe Global Markets U.S. Options Market Month-to-Date Volume Summary (June 16, 2022), available at *https://markets.cboe.com/us/options/market_statistics/.*

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[13] *See supra* note 9.

[14] *See supra* note 9.

[15] *Id.*

Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act [16] and Rule 19b–4(f)(2) thereunder,[17] because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2022–24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2022–24. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2022–24, and should be submitted on or before August 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17104 Filed 8–9–22; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A)(ii).

[17] 17 CFR 240.19b–4(f)(2).

[18] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 11802]

Public Meeting of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) Scientific Advisory Board

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the U.S. Department of State announces that the PEPFAR Scientific Advisory Board (SAB) will be holding a virtual meeting of the full board. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for both public viewing and comment.

DATES: The meeting will be held on Thursday, September 8, 2022, from approximately 8 a.m. to 1 p.m. (EDT) utilizing an online platform. Individuals wishing to view are asked to pre-register at *https://forms.gle/FrENNQyoX8Xav2zp8.*

ADDRESSES: The agenda is briefly summarized below and will also be sent to all registrants. It will also be posted on the PEPFAR SAB web page at *www.state.gov/scientific-advisory-board-pepfar* one week in advance of the meeting, along with instructions on how to access the meeting. Requests to view the meeting must be received no later than August 31, 2022. Requests for reasonable accommodations must be received no later than August 31, 2022. Requests made after August 31, 2022, will be considered but might not be able to be fulfilled.

FOR FURTHER INFORMATION CONTACT: Dr. Sara Klucking, Designated Federal Officer for the SAB, Office of the U.S. Global AIDS Coordinator and Health Diplomacy at *KluckingSR@state.gov* or (202) 615–4350.

SUPPLEMENTARY INFORMATION:

Background: The SAB is established under the general authority of the Secretary of State and the Department of State (''the Department'') as set forth in 22 U.S.C. 2656, and consistent with the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix). The SAB serves the U.S. Global AIDS Coordinator solely in an advisory capacity concerning scientific, implementation, and policy issues related to the global response to HIV/AIDS.

Agenda: SAB members will be discussing two topics: considerations for PEPFAR implementation of tools for recent HIV infection surveillance and considerations for PEPFAR implementation of the dapivirine vaginal ring. Meeting materials from prior SAB meetings may be accessed here: *www.state.gov/scientific-advisory-board-pepfar.*

Public comment: Members of the public who wish to view the meeting are asked to register directly at the link listed in the **DATES** and **ADDRESSES** section or by sending an email to Dr. Sara Klucking at *KluckingSR@state.gov* not later than August 31, 2022. Individuals are required to provide their name, email address, and organization. Individuals interested in making a public comment at the meeting should indicate interest with their registration. Registered members of the public wishing to make a comment will be permitted to participate in a comment period in accordance with the Chair's instructions. In addition, the Department will consider any written comments provided within 10 days after

the meeting to Dr. Sara Klucking at *KluckingSR@state.gov.*

Sara Klucking,

Director, Office of Research and Science, Office of the U.S. Global AIDS Coordinator and Health Diplomacy, Office of the Secretary of State, Department of State.

[FR Doc. 2022–17085 Filed 8–9–22; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF STATE

[Public Notice: 11808]

Bureau of Political-Military Affairs; Statutory Debarment Under the Arms Export Control Act and the International Traffic in Arms Regulations

ACTION: Notice.

SUMMARY: Notice is hereby given that the Department of State has imposed statutory debarment under the International Traffic in Arms Regulations (ITAR) on persons convicted of violating, or conspiracy to violate, the Arms Export Control Act (AECA).

DATES: Debarment imposed as of August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Jae E. Shin, Director, Office of Defense Trade Controls Compliance, Bureau of Political-Military Affairs, Department of State. (202) 632–2107.

SUPPLEMENTARY INFORMATION: Section 38(g)(4) of the AECA, 22 U.S.C. 2778(g)(4), restricts the Department of State from issuing licenses for the export of defense articles or defense services where the applicant, or any party to the export, has been convicted of violating the AECA or certain other statutes, enumerated in section 38 of the AECA, subject to a narrowly defined statutory exception. The Department refers to this restriction as a limitation on ''export privileges'' and implements a presumption of denial through section 127.11 of the ITAR.

In addition, section 127.7(b) of the ITAR provides for ''statutory debarment'' of any person who has been convicted of violating or conspiring to violate the AECA. Under this policy, persons subject to statutory debarment are prohibited from participating directly or indirectly in any activities that are regulated by the ITAR.

Statutory debarment is based solely upon conviction in a criminal proceeding, conducted by a United States court, and as such the administrative debarment procedures outlined in part 128 of the ITAR are not applicable.

It is the policy of the Department of State that statutory debarment as described in section 127.7(b) of the ITAR lasts for a three-year period following the date of conviction. Reinstatement from the policy of statutory debarment is not automatic, and in all cases the debarred person must submit a request to the Department of State and be approved for reinstatement from statutory debarment before engaging in any activities subject to the ITAR.

Department of State policy permits debarred persons to apply to the Director, Office of Defense Trade Controls Compliance, for reinstatement beginning one year after the date of the debarment. In response to a request for reinstatement from statutory debarment, the Department may determine either to rescind only the statutory debarment pursuant to section 127.7(b), or to both rescind the statutory debarment pursuant to section 127.7(b) of the ITAR and reinstate export privileges as described in section 127.11 of the ITAR. See 84 FR 7,411 (March 4, 2019) for discussion of the Department's policy regarding actions to both rescind the statutory debarment and reinstate export privileges. The reinstatement of export privileges can be made only after the statutory requirements of section 38(g)(4) of the AECA have been satisfied.

Certain exceptions, known as transaction exceptions, may be made to this debarment determination on a case-by-case basis. However, such an exception would be granted only after a full review of all circumstances, paying particular attention to the following factors: whether an exception is warranted by overriding U.S. foreign policy or national security interests; whether an exception would further law enforcement concerns that are consistent with the foreign policy or national security interests of the United States; or whether other compelling circumstances exist that are consistent with the foreign policy or national security interests of the United States, and that do not conflict with law enforcement concerns. Even if exceptions are granted, the debarment continues until subsequent reinstatement from statutory debarment.

Pursuant to section 38(g)(4) of the AECA and section 127.7(b) and (c)(1) of the ITAR, the following persons, having been convicted in a U.S. District Court, are denied export privileges and are statutorily debarred as of the date of this notice (Name; Date of Judgment; Judicial District; Case No.; Month/Year of Birth):

(1) Awer, Akeem Shonari; February 14, 2020; Southern District of Florida; 1:19–cr–20564; December 1990.

(2) Cabalceta, Oben; September 18, 2019; District of New Jersey; 1:19–cr–00296; May 1965.

(3) Camaj, Rrok Martin; February 28, 2020; Eastern District of Michigan; 2:19–cr–20403; July 1985.

(4) Guerra, Claudia; March 4, 2019; Southern District of Texas; 1:18–cr–00622; January 1992.

(5) Sin, Aydan; a.k.a. Hon Chak Gordon Sin; a.k.a. Andy Sin; a.k.a. Bullion Sin; October 05, 2021; Western District of New York; 1:17–cr–00090; January 1972.

(6) Sobrado, Roger; September 5, 2019; District of New Jersey; 1:18–cr–00615; May 1970.

(7) Wang, Shaohua; a.k.a. Eric Wang; February 3, 2020; Southern District of the California; 3:19–cr–01895; September 1982.

(8) Wang, Ye Sang; a.k.a. Ivy Wang; December 21, 2021; Southern District of California; 3:19–cr–01895; September 1984.

(9) Xie, Tuqiang; a.k.a. Tony Xie; March 30, 2022; Northern District of Illinois; 1:19–cr–00664; March 1962.

(10) Zhang, Jian; December 30, 2020; District of Arizona; 2:18–cr–01236; January 1976.

At the end of the three-year period following the date of this notice, the above-named persons remain debarred unless a request for reinstatement from statutory debarment is approved by the Department of State.

Pursuant to section 120.1(c) of the ITAR, debarred persons are generally ineligible to participate in activities regulated under the ITAR. Also, under section 127.1(d) of the ITAR, any person who has knowledge that another person is ineligible pursuant to section 120.1(c)(2) of the ITAR may not, without disclosure to and written approval from the Directorate of Defense Trade Controls, participate, directly or indirectly, in any ITAR-controlled transaction where such ineligible person may obtain benefit therefrom or have a direct or indirect interest therein.

This notice is provided for purposes of making the public aware that the persons listed above are prohibited from participating directly or indirectly in activities regulated by the ITAR, including any brokering activities and any export from or temporary import into the United States of defense articles, technical data, or defense services in all situations covered by the ITAR. Specific case information may be obtained from the Office of the Clerk for the U.S. District Courts mentioned

above and by citing the court case number where provided.

Kevin E. Bryant,

Acting Director, Office of Directives Management, Department of State.

[FR Doc. 2022–17123 Filed 8–9–22; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2013–0122; FMCSA–2013–0123; FMCSA–2013–0125; FMCSA–2014–0102; FMCSA–2014–0107; FMCSA–2015–0327; FMCSA–2015–0328; FMCSA–2015–0329; FMCSA–2017–0057; FMCSA–2017–0059; FMCSA–2017–0060; FMCSA–2018–0139; FMCSA–2019–0109; FMCSA–2019–0111; FMCSA–2020–0024; FMCSA–2020–0025]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 40 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these hard of hearing and deaf individuals to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided below. Comments must be received on or before September 9, 2022.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA–2013–0122, Docket No. FMCSA–2013–0123, Docket No. FMCSA–2013–0125, Docket No. FMCSA–2014–0102, Docket No. FMCSA–2014–0107, Docket No. FMCSA–2015–0327, Docket No. FMCSA–2015–0328, Docket No. FMCSA–2015–0329, Docket No. FMCSA–2017–0057, Docket No. FMCSA–2017–0059, Docket No. FMCSA–2017–0060, Docket No. FMCSA–2018–0139, Docket No. FMCSA–2019–0109, Docket No. FMCSA–2019–0111, Docket No. FMCSA–2020–0024, or Docket No. FMCSA–2020–0025 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/,* insert the docket number, FMCSA–2013–0122, FMCSA–2013–0123, FMCSA–2013–0125, FMCSA–2014–0102, FMCSA–2014–0107, FMCSA–2015–0327, FMCSA–2015–0328, FMCSA–2015–0329, FMCSA–2017–0057, FMCSA–2017–0059, FMCSA–2017–0060, FMCSA–2018–0139, FMCSA–2019–0109, FMCSA–2019–0111, FMCSA–2020–0024, or FMCSA–2020–0025 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2013–0122, Docket No. FMCSA–2013–0123, Docket No. FMCSA–2013–0125, Docket No. FMCSA–2014–0102, Docket No. FMCSA–2014–0107, Docket No. FMCSA–2015–0327, Docket No. FMCSA–2015–0328, Docket No. FMCSA–2015–0329, Docket No. FMCSA–2017–0057, Docket No. FMCSA–2017–0059, Docket No. FMCSA–2017–0060, Docket No. FMCSA–2018–0139, Docket No. FMCSA–2019–0109, Docket No. FMCSA–2019–0111, Docket No. FMCSA–2020–0024, or Docket No. FMCSA–2020–0025), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *www.regulations.gov/,* insert the docket number, FMCSA–2013–0122, FMCSA–2013–0123, FMCSA–2013–0125, FMCSA–2014–0102, FMCSA–2014–0107, FMCSA–2015–0327, FMCSA–2015–0328, FMCSA–2015–0329, FMCSA–2017–0057, FMCSA–2017–0059, FMCSA–2017–0060, FMCSA–2018–0139, FMCSA–2019–0109, FMCSA–2019–0111, FMCSA–2020–0024, or FMCSA–2020–0025 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–2013–0122, FMCSA–2013–0123, FMCSA–2013–0125, FMCSA–2014–0102, FMCSA–2014–0107, FMCSA–2015–0327, FMCSA–2015–0328, FMCSA–2015–0329, FMCSA–2017–0057, FMCSA–2017–0059, FMCSA–2017–0060, FMCSA–2018–0139, FMCSA–2019–0109, FMCSA–2019–0111, FMCSA–2020–0024, or FMCSA–2020–0025 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140

on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5–1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 3, 1971).

The 40 individuals listed in this notice have requested renewal of their exemptions from the hearing standard in § 391.41(b)(11), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 40 applicants has satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 40 drivers in this notice remain in good standing with the Agency. In addition, for commercial driver's license (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of these drivers for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of June and are discussed below.

As of June 17, 2022, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following 23 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Paul Aseka (TX)
James Bogart (KS)
Thomas Buretz (FL)
Forrest Carroll (OH)
Glenn Ferguson (TX)
Ariel Gonzalez (RI)
Nicholas Green (FL)
Richard Hadlock (IL)
Sean Hunt (SC)
Jesus Javier (NJ)
Larry Lang (TX)
Yoel Lopez-Perez (FL)
Bryan MacFarlane (OH)
Darren Nordquist (WI)
Anthony Panto (NJ)
Ernst Pratt (PA)
Brian Shoup (SC)
William Symonds (IL)
Steven Tipton (IA)
Daniel Tricolici (MA)
Wayne Turner (IL)
Fernando Velasquez (TX)
Scott Weeaks (OK)

The drivers were included in docket number FMCSA–2013–0122, FMCSA–2013–0123, FMCSA–2013–0125, FMCSA–2014–0107, FMCSA–2015–0327, FMCSA–2015–0328, FMCSA–2015–0329, FMCSA–2017–0057, FMCSA–2017–0059, FMCSA–2018–0139, FMCSA–2019–0109, FMCSA–2019–0111, or FMCSA–2020–0024. Their exemptions were applicable as of June 17, 2022 and will expire on June 17, 2024.

As of June 18, 2022, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Joshua Affholter (MI)
Gantulga Badarach (IL)
Awash Demoz (MD)
Muhammad Javed (IN)
Charles O'Bryan (NY)
Anna Ruiz (AZ)
Kyle Taylor (GA)

The drivers were included in docket number FMCSA–2020–0025. Their exemptions were applicable as of June 18, 2022 and will expire on June 18, 2024.

As of June 25, 2022, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following three individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Alfredo Ramirez (TX); Julie Ramirez (TX); and Hayden Teesdale (TX).

The drivers were included in docket number FMCSA–2014–0102. Their exemptions were applicable as of June 25, 2022 and will expire on June 25, 2024.

As of June 29, 2022, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Leroy Carter (OH)
Robert Cates (NM)
Brodey DiPasquale (MD)
Richard Fisher (PA)
Kimberly Foss (OR)
Marcel Paul (WA)
Jason Winemiller (IL)

The drivers were included in docket number FMCSA–2017–0060. Their

exemptions were applicable as of June 29, 2022 and will expire on June 29, 2024.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) each driver must report any crashes or accidents as defined in § 390.5; and (2) report all citations and convictions for disqualifying offenses under 49 CFR 383 and 49 CFR 391 to FMCSA; and (3) each driver prohibited from operating a motorcoach or bus with passengers in interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing requirements. Each exemption will be valid for 2 years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 40 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the hearing requirement in § 391.41(b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2022–17146 Filed 8–9–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. DOT–MARAD–2022–0167]

Request for Comments on the Renewal of a Previously Approved Information Collection: Effective U.S. Control (EUSC)/Parent Company

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: The Maritime Administration (MARAD) invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information to be collected will be used to aid in identifying oceangoing vessels that may be both useful and available to the Department of Defense for deploying U.S. military equipment (such as tanks and other tracked and wheeled vehicles) and the full range of supplies (including petroleum products and fuel) necessary to sustain a force in a foreign theater of operations. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Comments must be submitted on or before October 11, 2022.

ADDRESSES: You may submit comments identified by Docket No. DOT–MARAD–2022–0167 through one of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Search using the above DOT docket number and follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and docket number for this rulemaking.

Note: All comments received will be posted without change to *www.regulations.gov* including any personal information provided.

Comments are invited on: (a) whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Electronic Access and Filing

A copy of the notice may be viewed online at *www.regulations.gov* using the docket number listed above. A copy of this notice will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.FederalRegister.gov* and the Government Publishing Office's website at *www.GovInfo.gov.*

FOR FURTHER INFORMATION CONTACT: Katrina McRae, Vessel Transfer Specialist, Office of Sealift Support, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 366–3198, *katrina.mcrae@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Effective U.S. Control (EUSC)/Parent Company.

OMB Control Number: 2133–0511.

Type of Request: Renewal of a Previously Approved Information Collection.

Abstract: The Effective U.S. Control (EUSC)/Parent Company collection consists of an inventory of foreign-registered vessels owned by U.S. citizens. Specially, the collection consists of responses from vessel owners verifying or correcting vessel ownership data and characteristics found in commercial publications. The information obtained could be vital in a national or international emergency and is essential to the logistical support planning operations conducted by Maritime Administration officials.

Respondents: U.S. citizens who own foreign-registered vessels.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 60.

Estimated Number of Responses: 60.

Estimated Hours per Response: 1.

Annual Estimated Total Annual Burden Hours: 60.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.93.)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–17137 Filed 8–9–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0005; Notice 2]

Daimler Trucks North America, LLC, Denial of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition.

SUMMARY: Daimler Trucks North America, LLC (DTNA) has determined that certain model year (MY) 2011–2021 Thomas Built Saf-T-Liner HDX school buses do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 222, *School Bus Passenger Seating and Crash Protection.* DTNA filed a noncompliance report dated December 17, 2019, and later amended the report on January 16, 2020. DTNA subsequently petitioned NHTSA on January 16, 2020, (DTNA incorrectly dated their petition January 16, 2019) for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces and explains the denial of DTNA's petition.

FOR FURTHER INFORMATION CONTACT: Daniel Lind, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–7235, facsimile (202) 366–3081.

SUPPLEMENTARY INFORMATION:

I. Overview: Following notice from NHTSA of a failed compliance test, DTNA has determined that certain MY 2011–2021 Thomas Built Saf-T-Liner HDX school buses do not fully comply with the requirements of paragraph S5.2.3 of FMVSS No. 222, *School Bus Passenger Seating and Crash Protection* (49 CFR 571.222). DTNA filed a noncompliance report dated December 17, 2019, and later amended its report on January 16, 2020, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* DTNA subsequently petitioned NHTSA on January 16, 2020, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety. *See* 49 U.S.C. 30118(d), 30120(h); 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

Notice of receipt of DTNA's petition was published with a 30-day public comment period, on June 12, 2020, in the **Federal Register** (85 FR 35992). One comment was received. To view the petition and all related documents, members of the public can log onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/* and then follow the online search instructions to locate docket number NHTSA–2020–0005.

II. Buses Involved: Approximately 7,601 MY 2011–2021 Thomas Built Saf-T-Liner HDX school buses manufactured between October 21, 2009, and December 16, 2019 (the subject buses), are potentially involved.

III. Noncompliance: DTNA explains in its petition that the noncompliance at issue is that the subject school buses are equipped with a wall-mounted restraining barrier that does not meet the requirements specified in paragraph S5.2.3 of FMVSS No. 222. Specifically, when tested according to the specified test procedure, the restraining barrier did not meet the force/deflection curve or deflection requirements. DTNA contends that the restraining barrier failed to meet these requirements because the upper loading bar contacted the trim panel on the front entry door of the bus, which caused the upper loading bar force to exceed the allowable limit.

IV. Rule Requirements: Paragraph S5.2.3(a) of FMVSS No. 222 includes the requirement relevant to this petition. This requirement states that, ''[w]hen force is applied to the restraining barrier in the same manner as specified in paragraphs S5.1.3.1 through S5.1.3.4 for seating performance tests,'' the restraining barrier ''[f]orce/deflection curve shall fall within the zone specified in Figure 1.''

V. Summary of DTNA's Petition: The views and arguments described in this section, ''V. Summary of DTNA's Petition,'' are the views and arguments presented by DTNA and do not reflect the views of the Agency. In its petition, DTNA describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

In its petition, DTNA submits the following views and arguments:

1. *Background and description of the noncompliance:* DTNA states that it modified the restraining barrier design for the subject buses in October 2009, following an update to FMVSS No. 222, that increased the seat back height requirement to 24 inches. DTNA states that, for aesthetic purposes and not for functional or compliance reasons, it similarly chose to adjust the profiles (slope and angle) of the restraining barrier to match the new higher seatback height. To do so, DTNA added approximately 5⁄8 inch of foam padding to each side of the restraining barrier. The foam was added onto the outside of the frame of the barrier, which did not widen the frame structure itself. The additional padding is used for cosmetic purposes (to promote uniformity of design of the seat profiles at that time) and is not needed to provide protection beyond the construction of the restraining barrier itself.

2. *Analysis:* DTNA states that the purpose of the restraining barrier is to provide compartmentalization for occupants of the first row of school bus seats, where there is no seat back in a forward seat to offer protection. FMVSS No. 222 includes a series of performance requirements for school bus frontal barriers which include the distance between the barrier and the seat (S5.2.1), the barrier height and position (S5.2.2), and barrier forward performance (S5.2.3). The purpose of the barrier forward performance requirement at S5.2.3 is to ensure the front barrier can withstand the impact of certain set forces while, at the same time, maintaining component integrity.

3. *The forces measured in testing are a product of the test apparatus that would not occur in the real world.* DTNA states that the effect of the additional foam outside the restraining barrier frame was to slightly widen the restraining barrier. With a wider restraining barrier, the placement of the upper restraining barrier is moved outwards so that it now encounters the door frame trim. Because the restraining barrier is wider, based on its calculated placement per the test procedure, the corresponding length of the upper loading bar becomes longer than that of the prior design. When the upper loading bar is deployed, it contacts the front entrance door trim and causes the upper loading bar to exceed the force limits.

DTNA states that the behavior of the upper loading bar is a product of the test procedure and does not represent the behavior of the barrier in actual use conditions. Prior to the 2009 design change, there was an approximately two-inch gap at the height where the upper loading arm was placed. This prior design met the barrier forward performance requirements. Following the design change in 2009, that space was filled in with soft foam, but the effect of doing so did not have any impact on the performance or integrity of the barrier itself.

DTNA states that it has conducted its own analysis of the restraining barrier performance in the 2009 design tested by the Agency as well as the prior design. The results of that testing

demonstrate that the additional foam creates approximately 11 mm (.43 inches) of interference between the upper loading bar on the right side of the vehicle and the bus entrance door frame. The additional foam was not intended to and does not provide any safety or functional benefit. Even though the prior design of the restraining barrier left a small gap between the bus sidewall and the barrier itself, the barrier was more than sufficient to meet the performance forward requirements. The addition of foam for cosmetic purposes in 2009 does not deter from the safety of the barrier.

DTNA states that removing the additional 5/8 inches of foam padding would eliminate the potential for any interference with the upper loading bar as it then cannot come into physical contact with the doorframe. The previous small gap in space did not expose occupants to an increased risk of harm (as demonstrated by the lack of any reports from the field potentially related to this issue), and the more recent addition of the foam also does not create any safety concerns beyond the operation of the test itself.

4. *The current restraining barrier addresses the unreasonable risk to safety identified by FMVSS No. 222.* DTNA states that the purpose of a restraining barrier is to compartmentalize and contain passengers located in the first row of seats in the event of a crash or sharp deceleration. The forward performance test evaluates the strength of the restraining barrier in a forward impact and to deflect in a controlled manner as it absorbs the energy of the occupant striking the barrier.

DTNA states that the restraining barrier is intended to provide an equivalent level of compartmentalization as the seat back for the rearward seats. The safety benefit of compartmentalization is realized through the height of the restraining barrier (or seatback), and a restraining barrier that is too low could increase the likelihood that, in a forward crash, an occupant could be thrown over the barrier. This view is consistent with the requirement that the height and position of the restraining barrier match or ''coincide'' with that of the seatback. Because FMVSS No. 222 defines the unreasonable risk to safety as the potential for being thrown over the barrier, it is the height and position of the barrier that mitigate against this risk.

DTNA additionally states that, while the surface area of the barrier must at least coincide with the surface area of the seatback, any additional width of the barrier that extends beyond the frame of the barrier is surplus material that does not address the unreasonable risk to safety addressed by the standard. DTNA states that the Agency has previously recognized that a ''restraining barrier must therefore only coincide with or lie outside of the seatback surface required by S5.1.2. If a seat back surface exceeds the size required in Standard 222, the size of the restraining barrier need not coincide.'' (Ltr. from E. Jones, NHTSA, to L. Wort, Ill. Dept. of Transp. (Aug. 11, 1987).)[1] The reverse also holds true. For the subject buses, the surface area of the barrier is larger than that of the seat back and exceeds the area required by S5.2.1. While the restraining barrier surface area can be larger than the seat back, the unreasonable risk to safety is addressed by maximizing the effects of compartmentalization by ensuring the perimeter of the restraining barrier coincides with the surface area of the seatback.

DTNA states that the test procedure considers the need to assess the portion of the barrier that is intended to bear the force of the loading. DTNA believes that when creating the test procedure, the Agency intentionally limited the length of the loading bar to be approximately 4 inches shorter than the width of the seat back or restraining barrier. DTNA says NHTSA declined to reduce the size of the range to two inches because it wanted ''to ensure loads would be transferred to the seat structure without collapse of the seat back'' and to discourage manufacturers from adding a narrow structural member to meet the requirements. *See* 39 FR 27585 (July 30, 1974). In other words, the objective of the forward performance test is to measure the operation and structural integrity of the restraining barrier by ensuring the loads are concentrated in the core of the structure itself and not the periphery of the structure which could cause it to unnecessarily collapse. Thus, the additional foam installed outwards of the restraining barrier frame has no bearing on the forward performance of the restraining barrier.

5. DTNA states that it has corrected this issue in production by adjusting the location of the installation of the barrier by moving it away from the wall by 3/4 inch. Doing so ensures that in any future testing, the loading bar will not encounter the door frame.

6. Finally, DTNA states that it has used this seating design for over a decade. It is not aware of any consumer complaints or reports of accidents or injuries related to the forward displacement of the restraining barrier.

DTNA concludes its petition by again contending that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and requesting that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, be granted.

VI. Public Comment: NHTSA received one comment from the general public concerning DTNA's petition. The commenter believed NHTSA should deny DTNA's request on the basis that the subject vehicles failed to meet test requirements. NHTSA appreciates the commenter's input and, for the reasons described below, is denying DTNA's petition.

VII. NHTSA's Analysis

A. General Principles

Congress passed the National Traffic and Motor Vehicle Safety Act of 1966 (the ''Safety Act'') with the express purpose of reducing motor vehicle accidents, deaths, injuries, and property damage. *See* 49 U.S.C. 30101. To this end, the Safety Act empowers the Secretary of Transportation to establish and enforce mandatory Federal Motor Vehicle Safety Standards (FMVSS). *See* 49 U.S.C. 30111. The Secretary has delegated this authority to NHTSA. *See* 49 CFR 1.95.

NHTSA adopts an FMVSS only after it has determined that the performance requirements are objective, practicable, and meet the need for motor vehicle safety. *See* 49 U.S.C. 30111(a). Thus, there is a general presumption that the failure of a motor vehicle or item of motor vehicle equipment to comply with an FMVSS increases the risk to motor vehicle safety beyond the level deemed appropriate by NHTSA. To protect the public from such risks, manufacturers whose products fail to comply with an FMVSS are normally required to conduct a safety recall in which they must notify owners, purchasers, and dealers of the noncompliance and provide a free remedy. *See* 49 U.S.C. 30118–20. However, Congress recognized that, under some limited circumstances, a noncompliance could be ''inconsequential'' to motor vehicle safety. It therefore established a procedure under which NHTSA may consider whether it is appropriate to exempt a manufacturer from its notification and remedy (*i.e.,* recall) obligations. *See* 49 U.S.C. 30118(d), 30120(h). The Agency's regulations

[1] Available at: *https://isearch.nhtsa.gov/gm/87/nht87-2.66.html.*

governing the filing and consideration of petitions for inconsequentiality exemptions are set forth at 49 CFR part 556.

Under the Safety Act and Part 556, inconsequentiality exemptions may be granted only in response to a petition from a manufacturer, and then only after notice in the **Federal Register** and an opportunity for interested members of the public to present information, views, and arguments regarding the petition. In addition to considering public comments, the Agency will draw upon its own understanding of safety-related systems and its experience in deciding the merits of a petition. An absence of opposing argument and data from the public does not require NHTSA to grant a manufacturer's petition.

Neither the Safety Act nor part 556 define the term ''inconsequential.'' Rather, the Agency determines whether a particular noncompliance is inconsequential to motor vehicle safety based upon the specific facts before it in a particular petition. In some instances, NHTSA has determined that a manufacturer met its burden of demonstrating that a noncompliance is inconsequential to safety. For example, a label intended to provide safety advice to an owner or occupant may have a misspelled word, or it may be printed in the wrong format or the wrong type size. Where a manufacturer has shown that the discrepancy with the safety requirement is unlikely to lead to any misunderstanding, NHTSA has granted an inconsequentiality exemption, especially where other sources of correct information are available. *See, e.g.,* General Motors, LLC., Grant of Petition for Decision of Inconsequential Noncompliance, 81 FR 92963 (Dec. 20, 2016).

The burden of establishing the inconsequentiality of a failure to comply with a *performance* requirement in a standard—as opposed to a *labeling* requirement—is more substantial and difficult to meet. Accordingly, the Agency has found very few noncompliances with performance requirements to be inconsequential. Potential performance failures of safety-critical equipment, like seat belts or air bags, are rarely, if ever, found to be inconsequential.

An important issue to consider in determining inconsequentiality based upon NHTSA's prior decisions on noncompliance petitions is the safety risk to individuals who experience the type of event against which the recall would otherwise protect.[2] NHTSA also does not consider the absence of complaints or injuries to be demonstrative on the issue of whether the noncompliance is inconsequential to safety. The Agency has explained that ''the absence of a complaint does not mean there have not been any safety issues, nor does it mean that there will not be safety issues in the future.'' [3] Likewise, ''the fact that in past reported cases good luck and swift reaction have prevented many serious injuries does not mean that good luck will continue to work.'' [4]

Arguments that only a small number of vehicles or items of motor vehicle equipment are affected also have not resulted in granting an inconsequentiality petition.[5] Similarly, NHTSA has rejected petitions based on the assertion that only a small percentage of vehicles or items of equipment are likely to actually exhibit a noncompliance. The percentage of potential occupants that could be adversely affected by a noncompliance does not determine the question of inconsequentiality. Rather, the issue to consider is the outcome to an occupant who is exposed to the consequence of that noncompliance.[6]

[2] *See Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

[3] *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21666 (Apr. 12, 2016).

[4] *United States* v. *Gen. Motors Corp.,* 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it ''results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future'').

[5] *See Mercedes-Benz, U.S.A., L.L.C.; Denial of Application for Decision of Inconsequential Noncompliance,* 66 FR 38342 (July 23, 2001) (rejecting argument that noncompliance was inconsequential because of the small number of vehicles affected); *Aston Martin Lagonda Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 41370 (June 24, 2016) (noting that situations involving individuals trapped in motor vehicles—while infrequent—are consequential to safety); *Morgan 3 Wheeler Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21664 (Apr. 12, 2016) (rejecting argument that petition should be granted because the vehicle was produced in very low numbers and likely to be operated on a limited basis).

[6] *See Gen. Motors Corp.; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19900 (Apr. 14, 2004); *Cosco, Inc.; Denial of Application for Decision of Inconsequential Noncompliance,* 64 FR 29408, 29409 (June 1, 1999).

B. Response to DTNA's Arguments

NHTSA has reviewed DTNA's arguments that the subject noncompliance is inconsequential to motor vehicle safety. DTNA contends that the noncompliance of the passenger side barrier on the subject buses with the barrier forward performance requirements specified in paragraph S5.2.3 of FMVSS No. 222, poses little, if any, risk to motor vehicle safety. NHTSA does not agree. In reaching this conclusion, NHTSA considered the following:

The purpose of FMVSS No. 222 is to reduce the number of deaths and the severity of injuries that result from the impact of school bus occupants against structures within the vehicle during crashes and sudden driving maneuvers (49 CFR 571.222 S2). The requirements of S5.2.3 *Barrier Performance Forward* of FMVSS No. 222, at issue here are specific to the energy a barrier can absorb during an emergency event, and the rate at which such energy can be absorbed. These requirements are threefold: (1) a barrier must be able to absorb a minimum amount of energy within the first 356 mm of deflection,[7] (2) the rate of energy absorption must fall within a specified Force vs Deflection Zone,[8] and (3) the barrier, and its components, must not separate at any attachment point from the vehicle, nor interfere with normal door operation. In the present case, during NHTSA's compliance test of the barrier in question, the rate of energy absorption exceeded the upper limit of the Force vs Deflection Zone before absorbing the minimum required energy, thereby leading to a compliance test failure.

NHTSA does not agree that the 2009 design change to the subject buses did not have any impact on the barrier performance. DTNA states that it adjusted the profiles (slope and angle) of the barrier to match the new higher seatback height, in addition to adding approximately ⅝ inch of foam padding to each side of the barrier. DTNA did not provide evidence demonstrating that, when DTNA was considering the new barrier design, it tested the design or otherwise engaged in analyses to ensure compliance to the existing requirements of FMVSS No. 222. Similarly, DTNA did not provide evidence demonstrating that any testing

[7] The minimum energy required to be absorbed by the barrier is based on the number of designated seating positions, W, of the seat immediately behind the barrier. *See* 49 CFR 571.222 S5.1.3.4, S4.1(a).

[8] *See* 49 CFR 571.222 Figure 1.

or analyses were ever performed that took into account the obstruction between the new barrier design and front entrance door trim combination.[9] As such, NHTSA is not persuaded by DTNA's argument that the design change was only aesthetic and had no impact on the performance of the barrier, as no evidence was provided in support of this claim.

NHTSA also does not agree that the compliance test failure was caused by the upper loading bar contacting the front entrance door trim during the test. The barrier foam thickness is 3.5 inches (88 mm) and extends approximately 2 inches (51 mm) beyond the end of the loading bar. For the loading bar to contact the front entrance door trim, the loading bar would have had to compress 3.5 inches of foam to 0 inches to directly contact the front entrance door trim. Further, the loading bar is mounted to allow up to 30 degrees rotation in the horizontal plane, so that, when the barrier contacted the front entrance door trim and the foam began to compress on that side, the loading bar would rotate about its pivot point and reduce or eliminate any potential overlap between the loading bar and front entrance door trim. NHTSA therefore is not persuaded by DTNA's argument that the upper loading bar made contact with the front entrance door trim during the NHTSA compliance test because DTNA provided no evidence demonstrating how the 3.5 inches of foam could be compressed to 0 inches, and no analysis that accounted for the rotation of the loading bar away from the front entrance door trim.

NHTSA also does not agree with DTNA's argument that ''placement of the [upper loading bar] should be calculated based on the size of the barrier from the frame inwards and not include the surplus material that does not provide structure to the barrier.'' The NHTSA letter of interpretation which DTNA referenced in support of this argument [10] was responding to a question about whether the height of a barrier needed to match the height of the seat immediately behind a barrier, where the seat height was above the minimum required seat height specified in FMVSS No. 222. This letter of interpretation does not support DTNA's petition because energy absorption by the barrier was not at issue in the letter of interpretation. As such, NHTSA is not persuaded by DTNA's argument that the loading bar width should be calculated based on the barrier frame.

NHTSA does not agree with DTNA's argument regarding the length of the loading bar or its contention that ''the objective of the forward performance test is to measure the operation and structural integrity of the restraining barrier by ensuring the loads are concentrated in the core of the structure itself and not the periphery of the structure which could cause it to unnecessarily collapse.'' The history of FMVSS No. 222 and the requirements for the length of the loading bar show that FMVSS No. 222 was initially proposed as a new vehicle safety standard on February 22, 1973 (38 FR 4776). The preamble for this first proposed rule did not include any discussion on the length of the loading bar, and the proposed regulatory text stated that ''[t]he length of a loading bar is 4 inches less than the width of the seat back in each test.'' In response to comments received on the first proposed rule, a second proposed rule was published on July 30, 1974 (39 FR 27585). The preamble for the second proposed rule included a statement on the length of the loading bar, explaining that ''[t]he specified loading bar remains 4 inches shorter than the seat back width, despite several objections, to ensure that loads will be transferred to the seat structure without collapse of the seat back.'' The proposed regulatory text was slightly revised to provide that ''[t]he length of the loading bar is at least 4 inches less than the width of the seat back in each test.'' In response to comments received on the second proposed rule, a third proposed rule was published on April 23, 1975 (40 FR 17855). The preamble of the third proposed rule included a statement on the length of the loading bar, explaining that ''[t]he loading bar specifications have been tightened to require the bar to be 4 inches shorter than the seat back width, rather than 'at least 4 inches' shorter.' '' The proposed regulatory text in the third proposed rule was essentially reverted back to the text in the first proposed rule and provided that ''[t]he length of the loading bar is 4 inches less than the width of the seat back in each test.'' [11] In response to comments received on the third proposed rule, a fourth proposed rule was published on October 8, 1975 (40 FR 47141). The preamble of the fourth proposed rule included the following discussion specifically related to the loading bar length:

> Manufacturers also requested tolerances in positioning of the loading bar at 16 inches above the seating reference point and in the bar's 4-inch length.[12] As has often been stated in NHTSA interpretations on similar issues, such a request reflects a misunderstanding of the legal nature of the safety standards. They are not instructions, but performance levels that vehicles are required by law to be capable of meeting. Any tolerance in this context would be meaningless and misleading, since it would merely have the effect of stating a performance level that the product must meet when tested by the government, at one end or the other of the tolerance gap, but in a confusing manner. Recognizing that no measurement is perfectly precise, a manufacturer's testing should be designed to show, using this case as an example, that if the seat were tested with the loading bar at precisely 16 inches above the seating reference point, and with a bar exactly 4 inches long, the seat would meet the applicable requirements. This may be done in at least two different ways: (1) by using a test procedure that conforms so closely to the specified input measurements (16 inches, 4 inches, etc.)—that no significant differences in results could occur as a result of the differences between the actual input measurements and the specified ones, or (2)—by determining which ''side'' of the specified measurements is adverse to the product tested, and being sure that the actual input measurements deviate from the specified ones on the adverse side.

The proposed regulatory text was unchanged from the third proposed rule. Following public comment on the fourth proposed rule, a final rule was published on January 28, 1976 (41 FR 4018). The preamble of the final rule did not include any further discussion on the length of the loading bar, and the regulatory text remained unchanged from the third proposed rule. No additional rulemakings have impacted the requirement specified in paragraph S5.6 of FMVSS No. 222 regarding the length of the loading bar. Although DTNA states that ''NHTSA declined to reduce the size of the range [from four inches] to two inches because it wanted 'to ensure loads would be transferred to the seat structure without collapse of the seat back' and to discourage manufacturers from adding a narrow structural member to meet the requirements,'' the history of the rulemaking relating to this standard does not support this statement. This

[9] Manufacturers and testing laboratories may perform tests that are either ''in-bus'' or ''outside of bus'' for barrier and seat tests to evaluate barrier/seat performance. In the present case, the interaction between the barrier and the front entrance door trim is at issue, therefore only ''in-bus'' testing with the same relative placement of the barrier to the door trim would be appropriate for comparative purposes.

[10] Available at: *https://isearch.nhtsa.gov/gm/87/nht87-2.66.html.*

[11] The third proposed rule language matches the modern-day requirements specified in FMVSS No. 222 S5.6 (albeit in English units).

[12] In the preamble discussion of the fourth proposed rule for FMVSS No. 222, references to the loading bar being 4 inches long are actually in reference to the length of the loading bar being 4 inches less than the barrier width at the loading bar height.

same history shows that the Agency, at one time, contemplated *increasing* the size of the range at issue in its second proposed rule with the addition of the phrase ''at least,'' [13] but does not suggest that NHTSA ever contemplated *decreasing* the size of the range. Furthermore, although DTNA's argument implies that a *longer* loading bar may not concentrate loads to the barrier structure and may in fact lead to unnecessary collapse at the periphery of the barrier, DTNA provided no analysis or data supporting this claim. As such, NHTSA is not persuaded by DTNA's argument that ''the objective of the forward performance test is to measure the operation and structural integrity of the restraining barrier by ensuring the loads are concentrated in the core of the structure itself and not the periphery of the structure which could cause it to unnecessarily collapse.''

NHTSA's Decision: In consideration of the foregoing, NHTSA has decided that DTNA has not met its burden of persuasion that the subject FMVSS No. 222 noncompliance is inconsequential to motor vehicle safety. Accordingly, DTNA's petition is hereby denied, and DTNA is consequently obligated to provide notification of and free remedy for that noncompliance under 49 U.S.C. 30118 and 30120.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Anne L. Collins,

Associate Administrator for Enforcement.

[FR Doc. 2022–17132 Filed 8–9–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0030; Notice 2]

Collins Bus Corporation, Denial of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition.

SUMMARY: Collins Bus Corporation (Collins) has determined that certain model year (MY) 2012 2020 Ford and Chevrolet school buses do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 217, *Bus Emergency Exits and Window Retention and Release.* Collins filed a noncompliance report dated April 15, 2020. Collins subsequently petitioned NHTSA on April 30, 2020, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces the denial of Collins's petition.

FOR FURTHER INFORMATION CONTACT: Daniel Lind, NHTSA, Office of Vehicle Safety Compliance, telephone (202) 366–7235.

SUPPLEMENTARY INFORMATION:

I. Overview: Collins has determined that certain MY 2012–2020 Ford and Chevrolet school buses do not fully comply with the requirements of paragraph S5.5.3(b) of FMVSS No. 217, *Bus Emergency Exits and Window Retention and Release* (49 CFR 571.217). Collins filed a noncompliance report dated April 15, 2020, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Collins subsequently petitioned NHTSA on April 30, 2020, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

Notice of receipt of Collins's petition was published in the **Federal Register** (85 FR 84463) with a 30-day public comment period, on December 28, 2020. No comments were received. To view the petition and all supporting documents, log onto the Federal Docket Management System (FDMS) website at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2020–0030.''

II. Buses Involved: Approximately 11,079 MY 2012–2020 Ford and Chevrolet school buses manufactured by Collins, as the final stage manufacturer, between February 2, 2012, and April 3, 2020, are potentially involved:

- Ford TH 400
- Ford Sh416, models SL, SH, DH, DE, TH, and TL
- Chevrolet DE516
- Chevrolet DH516
- Chevrolet DH500
- Ford TL 400
- Ford T24
- Chevrolet DH400

III. Noncompliance: Collins explains that the noncompliance is that the letter height for the operating instructions label describing the motions necessary to unlatch and open the emergency exits in the subject school buses does not fully comply with the requirements set forth in paragraph S5.5.3(b) of FMVSS No. 217. Specifically, the operating instructions describing the motions necessary to unlatch and open the emergency window exits are only eight (8) millimeters in height rather than the required one (1) centimeter.

IV. Rule Requirements: Paragraph S5.5.3(b) of FMVSS No. 217 includes the requirements relevant to this petition. Paragraph S5.5.3(b) requires that concise operating instructions describing the motions necessary to unlatch and open the emergency exit shall be located within 15 centimeters of the release mechanism on the inside surface of the bus. These instructions shall be in letters at least 1 centimeter high and of a color that contrasts with its background.

V. Summary of Collins's Petition: The following views and arguments presented in this section, ''V. Summary of Collins's Petition,'' are the views and arguments provided by Collins and do not reflect the views of the Agency. Collins describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, Collins offers the following reasoning:

1. The Noncompliance is Inconsequential to Motor Vehicle Safety: Collins states that the 2-millimeter deficiency in the letter height is inconsequential to motor vehicle safety. The actual height of the emergency window exit operating instructions letters—eight (8) millimeters—is 80 percent of the height required by FMVSS No. 217 (ten (10) millimeters). NHTSA has previously granted inconsequential noncompliance petitions for labeling defects across various motor vehicle safety standards, including for more significant lettering height deficiencies:

- *Notice Granting Petition by Kia Motors:* Letters as little as 53.1 percent of the minimum height requirement. *See* 69 FR 41333 (July 8, 2004) (Docket No. NHTSA–2004–17439).
- *Notice Granting Petition by General Motors:* Lettering height 76.3 percent of the minimum height requirement. *See* 81 FR 92963 (Docket No. NHTSA–2016–0093).
- *Notice Granting Petition by Hyundai:* Letters as little as 78.1 percent of the minimum height requirement. *See* 69 FR 41568 (Docket No. NHTSA–2004–17439).
- *Notice Granting Petition by Mercedes-Benz:* Letters ''about

[13] For clarity, *increasing* the size of the range at issue (which is the length of the loading bar relative to the width of the barrier) would correspond to a *shorter* loading bar. On the same note, *decreasing* the size of the range, would correspond to a *longer* loading bar.

78[percent] of the minimum height required for such letters.'' Pet. at 3 (emphasis omitted). *See* 67 FR 72026 (Docket No. NHTSA–2002–12544).

2. Further, the instruction label includes the words ''Emergency Exit'' in letters with a height of 11 millimeters, which not only meets but substantially exceeds the 1-centimeter requirement. *See* 67 FR 72026 (noting that some of the letters did meet the minimum height requirements in finding that insufficient height of other letters did not have an adverse effect on vehicle safety).

3. Collins claims that the height discrepancy does not affect the readability of the instructions. *See* 67 FR 72026 (finding that letters which were roughly 78 percent of the required size (which required size was nearly one-third of the relevant one-centimeter letter height requirement at issue here) would not ''degrade the legibility'' of the words); 81 FR 92964 (finding ''the lettering height for the park brake applied indicator 'Park' at 2.44 mm versus the FMVSS No. 135 requirement of 3.2 mm poses little if any risk to motor vehicle safety'').

4. Further, Collins says the discrepancy does not compromise the conspicuity of the instructions. The instructions are not only in a color that sharply contrasts with their background (red) as required by FMVSS No. 217, the letters are additionally in bold and block capital letters, which is not required by the standard but which preserves the 8-millimeter height across the width of the words and increases the visibility of the instructions. *See* 81 FR 92964 (finding the use of all capitalized letters, where not required, provided ''a more pronounced indicator''). And as noted above, some of the words in the instruction label (*i.e.,* ''Emergency Exit'') not only meet but exceed the minimum height requirement, thereby increasing the visibility of the instructions.

5. Collins states that NHTSA has previously granted petitions for inconsequential noncompliance under FMVSS No. 217 for conditions that present a more direct safety risk than the potential safety risk (if any) created here. *See* New Flyer of America, Inc.; Grant of Application for Decision of Inconsequential Noncompliance, 63 FR 32694 (granting petition for inconsequential noncompliance where buses were manufactured with only one emergency exit instead of two); IC Corporation, Grant of Petition for Decision of Inconsequential Noncompliance, 70 FR 24464 (granting petition for inconsequential noncompliance where school buses were manufactured with two emergency doors under the same post and roof bow panel space).

6. Finally, Collins states that the emergency window exit instructions on the affected vehicles meet all other labeling requirements of FMVSS No. 217 and do not affect the actual operation of the emergency window exit, and Collins has not received any complaints regarding the size or visibility of the instructions and is not aware of any injuries associated with the size or visibility of the instructions. Collins has corrected the noncompliance in all buses remaining within its possession.

Collins concludes by again contending that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

Collins's complete petition and all supporting documents are available by logging onto the FDMS website at *https://www.regulations.gov* and by following the online search instructions to locate the docket number as listed in the title of this notice.

VII. NHTSA's Analysis:

A. General Principles

Congress passed the National Traffic and Motor Vehicle Safety Act of 1966 (the Safety Act) with the express purpose of reducing motor vehicle accidents, deaths, injuries, and property damage. *See* 49 U.S.C. 30101. To this end, the Safety Act empowers the Secretary of Transportation to establish and enforce mandatory Federal Motor Vehicle Safety Standards (FMVSS). *See* 49 U.S.C. 30111. The Secretary has delegated this authority to NHTSA. *See* 49 CFR 1.95.

NHTSA adopts a FMVSS only after the Agency has determined that the performance requirements are objective and practicable and meet the need for motor vehicle safety. *See* 49 U.S.C. 30111(a). Thus, there is a general presumption that the failure of a motor vehicle or item of motor vehicle equipment to comply with a FMVSS increases the risk to motor vehicle safety beyond the level deemed appropriate by NHTSA through the rulemaking process. To protect the public from such risks, manufacturers whose products fail to comply with a FMVSS are normally required to conduct a safety recall under which they must notify owners, purchasers, and dealers of the noncompliance and provide a free remedy. *See* 49 U.S.C. 30118–30120. However, Congress has recognized that, under some limited circumstances, a noncompliance could be ''inconsequential'' to motor vehicle safety. It therefore established a procedure under which NHTSA may consider whether it is appropriate to exempt a manufacturer from its notification and remedy (*i.e.,* recall) obligations. *See* 49 U.S.C. 30118(d), 30120(h). The Agency's regulations governing the filing and consideration of petitions for inconsequentiality exemptions are set out at 49 CFR part 556.

Under the Safety Act and Part 556, inconsequentiality exemptions may be granted only in response to a petition from a manufacturer, and then only after notice in the **Federal Register** and an opportunity for interested members of the public to present information, views, and arguments on the petition. In addition to considering public comments, the Agency will draw upon its own understanding of safety-related systems and its experience in deciding the merits of a petition. An absence of opposing argument and data from the public does not require NHTSA to grant a manufacturer's petition.

Neither the Safety Act nor Part 556 define the term ''inconsequential.'' Rather, the Agency determines whether a particular noncompliance is inconsequential to motor vehicle safety based upon the specific facts before it in a particular petition. An important issue to consider in determining inconsequentiality based upon NHTSA's prior decisions on noncompliance issues was the safety risk to individuals who experience the type of event against which the recall would otherwise protect.[1] NHTSA also does not consider the absence of complaints or injuries to show that the issue is inconsequential to safety. The Safety Act is preventive, and manufacturers cannot and should not wait for deaths or injuries to occur in their vehicles before they carry out a recall. *See, e.g., United States* v. *Gen. Motors Corp.,* 565 F.2d 754, 759 (D.C. Cir. 1977). Indeed, the very purpose of a recall is to protect individuals from risk. *See id.* ''Most importantly, the

[1] *See Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

absence of a complaint does not mean there have not been any safety issues, nor does it mean that there will not be safety issues in the future.'' [2] ''[T]he fact that in past reported cases good luck and swift reaction have prevented many serious injuries does not mean that good luck will continue to work.'' [3] Arguments that only a small number of vehicles or items of motor vehicle equipment are affected have also not justified granting an inconsequentiality petition.[4] Similarly, NHTSA has rejected petitions based on the assertion that only a small percentage of vehicles or items of equipment are likely to actually exhibit a noncompliance. The percentage of potential occupants that could be adversely affected by a noncompliance does not determine the question of inconsequentiality. Rather, the issue to consider is the consequence to an occupant who is exposed to the consequence of that noncompliance.[5]

B. Response to Collins's Arguments

NHTSA reviewed Collins's arguments that the subject noncompliance is inconsequential to motor vehicle safety. Collins contends that the letter heights of the operating instructions describing the motions necessary to unlatch and open the emergency window exit not meeting the Emergency Exit Identification requirements as specified in paragraph S5.5.3(b) of FMVSS No. 217, poses little, if any, risk to motor vehicle safety. NHTSA does not agree. NHTSA's decision considered the following:

The purpose of FMVSS No. 217 is to minimize the likelihood of occupants being thrown from the bus and to provide a means of readily accessible emergency egress (*See* 49 CFR 571.217 S2). The Emergency Exit Identification requirements at S5.5.3(b) of FMVSS No. 217, at issue here, are specific to the operating instructions required for emergency exits in school buses. These requirements are fourfold: (1) operating instructions must be ''concise'' and describe ''the motions necessary to unlatch and open the emergency exit,'' (2) operating instructions must ''be located within 15 centimeters of the release mechanism on the inside surface of the bus,'' (3) operating instructions must ''be in letters at least 1 centimeter high,'' and (4) operating instructions must be ''of a color that contrasts with [their] background.''

In the present case, the instruction labels at issue contain the following text: ''EMERGENCY EXIT LIFT HANDLE PUSH WINDOW TO OPEN.'' The labels therefore contain operating instructions (LIFT HANDLE PUSH WINDOW TO OPEN) which concisely describes the motions necessary to unlatch and open the emergency exit. The labels are located within 15 centimeters of the release mechanism on the inside surface of the bus and are of a color that contrasts with their background. However, although the words ''EMERGENCY EXIT'' on the instruction labels meet the minimum letter height requirement, the remaining text containing the actual operating instructions fail to meet the letter height requirement at S5.5.3(b)—the operating instructions do not consist of ''letters at least 1 centimeter high.'' This point is further discussed below.

Regarding Collins's argument that the words ''EMERGENCY EXIT'' have a letter height of 11 mm ''which not only meets but substantially exceeds the 1-centimeter requirement,'' Collins's argument is not compelling in how the difference of 1 mm in the words ''EMERGENCY EXIT'' improves the legibility of the words ''LIFT HANDLE PUSH WINDOW TO OPEN'' having a letter height of only 8 mm, a full 2 mm below the 1-centimeter requirement. Further, NHTSA notes that Collins's statement that 1 mm of letter height is ''substantial'' when above the 1 cm requirement, however ''the 2-millimeter deficiency in the letter height is inconsequential to motor vehicle safety,'' indicates a lack of consistency in Collins's argument. Collins also referenced a previous petition granted by NHTSA in support of this claim, which is addressed below, and which is unrelated to school bus emergency exit identification and operation. As such, NHTSA is not persuaded by Collins's argument that having the words ''EMERGENCY EXIT'' being 1 mm taller than the letter height requirements at S5.5.3(b) mitigates the noncompliance for the operating instructions ''LIFT HANDLE PUSH WINDOW TO OPEN'' being 2 mm shorter than the requirement. Furthermore, NHTSA is not persuaded by Collins's argument that a 2 mm measurement is any less substantial than a 1 mm measurement, as no evidence was provided in support of this claim.

Regarding the readability of the operating instructions, NHTSA does not agree with Collins that the readability of the operating instructions is unaffected by the noncompliance with the letter height requirement. Collins referenced two previous petitions granted by NHTSA in support of this claim, which are addressed below, that are unrelated to school bus emergency exit identification and operation. As such, NHTSA is not persuaded by Collins's argument that the readability of the operating instructions is unaffected by the noncompliance with the letter height requirement, as no evidence was provided in support of this claim.

Regarding the conspicuity of the operating instructions, NHTSA agrees with Collins that the operating instructions are ''in a color that sharply contrasts with their background (red)'' and are ''in bold and block capital letters, which is not required by the standard but which preserves the 8-millimeter height across the width of the words and increases the visibility of the instructions,'' but does not agree with Collins that compliance with the conspicuity requirements for the operating instructions impacts compliance with the letter height requirements for the operating instructions for emergency exits in school buses. Collins referenced a previous petition granted by NHTSA in support of this claim, which is addressed below, that are unrelated to school bus emergency exit identification and operation. As such, NHTSA is not persuaded by Collins's argument that meeting the conspicuity requirements for the operating instructions mitigates the noncompliance with the letter height requirement, as no evidence was provided in support of this claim.

C. Remaining Arguments

Collins referenced six inconsequential noncompliance petitions NHTSA had previously granted to support its petition.

The first petition, from Kia Motors America, Inc., and Kia Motors Corp.

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[2] *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21666 (Apr. 12, 2016).

[3] *United States* v. *Gen. Motors Corp.,* 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it ''results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future'').

[4] *See Mercedes-Benz, U.S.A., L.L.C.; Denial of Application for Decision of Inconsequential Noncompliance,* 66 FR 38342 (July 23, 2001) (rejecting argument that noncompliance was inconsequential because of the small number of vehicles affected); *Aston Martin Lagonda Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 41370 (June 24, 2016) (noting that situations involving individuals trapped in motor vehicles—while infrequent—are consequential to safety); *Morgan 3 Wheeler Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21664 (Apr. 12, 2016) (rejecting argument that petition should be granted because the vehicle was produced in very low numbers and likely to be operated on a limited basis).

[5] *See Gen. Motors Corp.; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19900 (Apr. 14, 2004); *Cosco, Inc.; Denial of Application for Decision of Inconsequential Noncompliance,* 64 FR 29408, 29409 (June 1, 1999).

(Kia) (*See* 69 FR 41333), involved passenger vehicles which did not meet the letter height requirements for brake system warning lights, specifically for the abbreviation ''ABS'' and in some cases the word ''brake,'' as required by FMVSS No. 101, 105, and 135. In this case, these passenger vehicles did not meet the minimum letter height requirement of 3.2 mm. The Agency decided that ''due to the positioning, color, use of the ISO symbol, and combined size of both the lettering and symbols, it is very unlikely that a vehicle user would either fail to see or fail to understand the meaning of the brake or ABS warning light in the affected vehicles'' and granted the petition. NHTSA does not agree that granting this prior petition supports granting Collins's petition here, for four reasons: (1) compliance with FMVSS No. 217 was not at issue, (2) emergency exit identification within the vehicle was not at issue, (3) the warning lights in Kia's petition both ''illuminated in red (brake warning light) or yellow (ABS light)'' and also ''include[d] an International Standards Organization (ISO) symbol combined with the word 'brake' or the abbreviation 'ABS,''' which are two features distinctly different from the emergency exit labels at issue here (which do not illuminate or contain any symbol), and (4) the warning lights in Kia's petition were related to the driver's attention, whereas the emergency exit operating instructions in Collins's petition is for school bus passenger use in the event of an emergency.

The second petition, from General Motors, LLC (GM) (*See* 81 FR 92963), involved passenger vehicles which did not meet the letter height requirements for the park brake telltale (identified by the word ''PARK''), as required by FMVSS No. 101 and 135. In this case, these passenger vehicles did not meet the minimum letter height requirement of 3.2 mm for the word ''PARK.'' The Agency decided that ''[i]llumination of both the 'PARK' indicator combined with the information center statement 'Park Brake Set' provides ample communication to the driver that the parking brake has been applied,'' and granted the petition. NHTSA does not agree that granting this prior petition supports granting Collins's petition here, for five reasons: (1) compliance with FMVSS No. 217 was not at issue, (2) emergency exit identification within the vehicle was not at issue, (3) the park brake telltale lights in GM's petition ''illuminated,'' which is a feature distinctly different from the emergency exit labels at issue here (which do not illuminate), (4) activation of the park brake telltale light in GM's petition would simultaneously activate a second illuminated message, which is a feature distinctly different from the emergency exit labels at issue here (which do not activate a second message), and (5) the park brake telltale lights in GM's petition were related to the driver's attention, whereas the emergency exit operating instructions in Collins's petition is for school bus passenger use in the event of an emergency.

The third petition, from Hyundai Motor Company (Hyundai) (*See* 69 FR 41668), involved passenger vehicles which did not meet the letter height requirements for the abbreviation ''ABS'' and in other cases the word ''brake,'' as required by FMVSS No. 105 and 135. In this case, these passenger vehicles did not meet the minimum letter height requirement of 3.2 mm. The Agency decided that ''[d]ue to the positioning, color, use of the ISO symbol, and combined size of both the lettering and symbols, it is very unlikely that a vehicle user would either fail to see or fail to understand the meaning of the brake or ABS warning light in the affected vehicles,'' and granted the petition. NHTSA does not agree that granting this prior petition supports granting Collins's petition here, for four reasons: (1) compliance with FMVSS No. 217 was not at issue, (2) emergency exit identification within the vehicle was not at issue, (3) the warning lights in Hyundai's petition both ''illuminated'' and also included an ''International Standards Organization (ISO) symbol for the ABS,'' which are two features distinctly different from the emergency exit labels at issue here (which do not illuminate or contain any symbol), and (4) the warning lights in Hyundai's petition were related to the driver's attention, whereas the emergency exit operating instructions in Collins's petition is for school bus passenger use in the event of an emergency.

The fourth petition, from Mercedes-Benz, U.S.A., Inc. (MBUSA) (*See* 67 FR 72026), involved passenger vehicles which did not meet the letter height requirements for the brake warning indicator lamp, as required by FMVSS No. 135. In this case, these passenger vehicles did not meet the minimum letter height requirement of 3.2 mm for the letters ''r,'' ''a,'' and ''e'' in the word ''Brake.'' The Agency decided that ''the Agency does not believe that the noncompliance will degrade the legibility of the brake malfunction telltale, or will have an adverse effect on vehicle safety,'' and granted the petition. NHTSA does not agree that granting this prior petition supports granting Collins's petition here, for six reasons: (1) compliance with FMVSS No. 217 was not at issue, (2) emergency exit identification within the vehicle was not at issue, (3) the brake warning indicator lamp in MBUSA's petition ''illuminated,'' which is a feature distinctly different from the emergency exit labels at issue here (which do not illuminate), (4) activation of the brake warning indicator lamp in MBUSA's petition would simultaneously activate a second illuminated message, which is a feature distinctly different from the emergency exit labels at issue here (which do not activate a second message), (5) activation of the second illuminated message in MBUSA's petition would ''[trigger] an audible signal,'' which is a feature distinctly different from the emergency exit labels at issue here (which do not trigger an audible signal), and (6) the brake warning indicator lamp in MBUSA's petition was related to the driver's attention, whereas the emergency exit operating instructions in Collins's petition is for school bus passenger use in the event of an emergency.

The fifth petition, from New Flyer of America, Inc. (*See* 63 FR 32694), involved transit buses that had only one emergency exit on the right side of the bus instead of two, as required by FMVSS No. 217. In this case, these buses had 3.28 times the required exit area, with two emergency exit windows on the left side, one emergency exit window on the right side and two roof exits. Thus, the buses had the minimum number of emergency exits required by FMVSS No. 217. However, these exits were not distributed properly. Instead of a second emergency exit on the right side, these buses had an additional roof exit. The Agency decided that the additional roof exit provided for an additional level of safety during a rollover event and granted the petition. NHTSA does not agree that the granting of this prior petition supports granting Collins's petition here, because emergency exit identification and operation within the vehicle was not at issue.

The sixth petition, from IC Corporation (IC) (*See* 70 FR 24464), involved school buses where two side emergency exit doors were located opposite each other within the same post and roof bow panel space. IC argued that the requirement prohibiting two exit doors from being located in this manner appeared to be related to the structural integrity of a bus body with this configuration. IC indicated that it had no reports of any structural failures in the area around the emergency doors

but stated that it would extend to owners of the noncompliant vehicles a 15-year warranty for any structural or panel failures related to the location of the doors. NHTSA agreed with IC that, in this case, the noncompliance did not compromise safety in terms of emergency exit capability in proportion to maximum occupant capacity, access to side emergency doors, visibility of the exits, or the ability of bus occupants to exit after an accident. NHTSA does not agree that the granting of this prior petition supports granting Collins's petition here, because emergency exit identification and operation within the vehicle was not at issue.

None of the previous six petitions Collins provided in support of its current petition were related to labeling for emergency egress of school buses. Emergency egress occurs under states of emergency, which may include fire, smoke, panicked children, etc. As such, the dilution of these emergency egress marking requirements in school buses is consequential to motor vehicle safety.

NHTSA's Decision: In consideration of the foregoing, NHTSA has decided that Collins has not met its burden of persuasion that the subject FMVSS No. 217 noncompliance is inconsequential to motor vehicle safety. Accordingly, Collins's petition is hereby denied and Collins is consequently obligated to provide notification of and free remedy for that noncompliance under 49 U.S.C. 30118 and 30120.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Anne L. Collins,

Associate Administrator for Enforcement.

[FR Doc. 2022–17135 Filed 8–9–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0096; Notice 1]

Hercules Tire & Rubber Company, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Hercules Tire & Rubber Company, (Hercules), has determined that certain Hercules Power ST2 radial trailer tires do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More Than 4,536 Kilograms (10,000 Pounds), Specialty Tires, and Tires for Motorcycles.* Hercules filed an original noncompliance report dated December 9, 2021, and amended the report on December 14, 2021, and March 9, 2022. Hercules petitioned NHTSA on December 16, 2021, and amended the petition on March 9, 2022, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces receipt of Hercules's petition.

DATES: Send comments on or before September 9, 2022.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and may be submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal Holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Follow the online instructions for submitting comments.
- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the dockets. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 19477–78).

FOR FURTHER INFORMATION CONTACT: Jayton Lindley, General Engineer, NHTSA, Office of Vehicle Safety Compliance, (325) 655–0547.

SUPPLEMENTARY INFORMATION:

I. Overview: Hercules determined that certain Hercules Power ST2 radial trailer tires do not fully comply with the requirements of paragraph S6.5(b) of FMVSS No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More Than 4,536 Kilograms (10,000 Pounds), Specialty Tires, and Tires for Motorcycles* (49 CFR 571.119).

Hercules filed an original noncompliance report dated December 9, 2021, and amended the report on December 14, 2021, and March 9, 2022, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Hercules petitioned NHTSA on December 16, 2021, and amended its petition on March 9, 2022, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

This notice of receipt of Hercules's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or another exercise of judgment concerning the merits of the petition.

II. Vehicles Involved: Approximately 67 Hercules Power ST2 size ST205/75R15 radial trailer tires, manufactured between November 23, 2020, and November 29, 2020, are potentially involved:

III. Noncompliance: Hercules explains that the noncompliance is due to a mold error in which the subject tires contain a tire identification number (TIN) with the second and third numerical symbols in the date code are transposed and therefore, do not meet the requirements of paragraph S6.5(b) of FMVSS No. 139. Specifically, the TIN on the subject tires incorrectly states the date code as ''4280,'' when it should state ''4820.''

IV. Rule Requirements: Paragraph S6.5(b) of FMVSS No. 119 and Part 574.5(b)(3) include the requirements relevant to this petition. FMVSS No. 119 states the TIN must meet the requirements set forth in Part 574. Part 574.5(b)(3), states that the date code portion of the TIN must identify the week and year of manufacture. The first and second symbols of the date code must identify the week of the year by using ''01'' for the first full calendar week in each year, ''02'' for the second full calendar week, and so on. The third and fourth symbols of the date code must identify the last two digits of the year of manufacture.

V. Summary of Hercules's Petition: The following views and arguments presented in this section, ''V. Summary of Hercules's Petition,'' are the views and arguments provided by Hercules. They have not been evaluated by the Agency and do not reflect the views of the Agency. Hercules describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

Hercules explains that the subject noncompliance does not result in an increased risk to safety because the incorrect date code (''4280'') indicates that the subject tires were manufactured in the 42nd week of either 1980 or 2080. According to Hercules, ''[t]he only years that a year code of 80 could potentially relate to are 1980, over 40 years ago, or 2080, which is so far into the future to be implausible.'' Hercules claims the subject noncompliance would not cause a consumer to use the tire beyond its recommended maximum service life because a ''consumer would not simply assume that the year code listed on the tire is in fact the correct date and be misled.'' Hercules says that if a consumer did follow the date code listed on the subject tires, ''the guidance provided on NHTSA's website,'' informs consumers that ''tires should be replaced within six to 10 years regardless of treadwear.'' In addition, because the year the date code indicates is implausible if a dealer were to store the subject tires for multiple years before selling them, Hercules believes ''there is no risk of misleading the consumer about the age of the tire.''

Hercules says that while the second and third symbols in the date code were transposed in the TIN, ''all other content within the TIN is accurate and the tires otherwise conform to the performance requirements applicable to specialty trailer tires.'' Hercules states that the subject noncompliance ''affects only the single week of tire production and the condition has been corrected in production.''

Hercules states that granting its petition would be consistent with similar decisions that NHTSA has previously granted for inconsequentiality. Hercules cited the following prior petitions that NHTSA has granted, and that Hercules believes support the granting of its petition:

- Bridgestone Firestone North America Tire, LLC, Grant of Petition for Decision of Inconsequential Noncompliance, 71 FR 4396 (January 26, 2006);
- Bridgestone/Firestone, Inc., Grant of Application for Decision That Noncompliance Is Inconsequential to Motor Vehicle Safety, 66 FR 45076 (August 27, 2001).

Hercules believes that NHTSA's primary concern related to mislabeled or inaccurate TINs is the potential for adverse safety consequences due to consumers using aged tires that are beyond the manufacturer's recommended service life and regardless of the service condition of the tire. *See Cooper Tire & Rubber Company,* 86 FR 47726 (August 26, 2021).

In the event of a recall, Hercules says that it has taken steps so that it would be able to identify the subject tires and notify consumers. Hercules believes that this further supports the granting of its petition because it says NHTSA has stated in prior grants of inconsequentiality petitions that the purpose of a date code is to identify the tire so that, if necessary, the appropriate action can be taken in the interest of public safety—such as a safety recall notice. Hercules says that consumers will be able to register the tire with the noncompliant TIN and Hercules's database will identify the tire ''as having been produced in calendar week 48, calendar year 2020.'' If necessary for a recall, Hercules says it would be able to contact consumers and include the TIN ''as it is listed on the tire sidewall so that consumers could check the recall notification against the tire sidewall for verification purposes.

Hercules concludes by stating its belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety and its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject tires that Hercules no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve tire distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after tires notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke, III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2022–17131 Filed 8–9–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Federal Motor Vehicle Theft Prevention Standard; Mazda Motor Corporation

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the Mazda Motor Corporation (Mazda) petition for exemption from the Federal Motor Vehicle Theft Prevention Standard (theft prevention standard) for its confidential vehicle line beginning in model year (MY) 2024. The petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard. Mazda also requested confidential treatment for specific information in its petition.

Therefore, no confidential information provided for purposes of this notice has been disclosed.

DATES: The exemption granted by this notice is effective beginning with the 2024 model year.

FOR FURTHER INFORMATION CONTACT: Carlita Ballard, Office of International Policy, Fuel Economy, and Consumer Programs, NHTSA, West Building, W43–439, NRM–310, 1200 New Jersey Avenue SE, Washington, DC 20590. Ms. Ballard's phone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: Under 49 U.S.C. Chapter 331, the Secretary of Transportation (and the National Highway Traffic Safety Administration (NHTSA) by delegation) is required to promulgate a theft prevention standard to provide for the identification of certain motor vehicles and their major replacement parts to impede motor vehicle theft. NHTSA promulgated regulations at 49 CFR part 541 (theft prevention standard) to require parts-marking for specified passenger motor vehicles and light trucks. Pursuant to 49 U.S.C. 33106, manufacturers that are subject to the parts-marking requirements may petition NHTSA, by delegation, for an exemption for a line of passenger motor vehicles equipped with an antitheft device as standard equipment that NHTSA decides is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements. In accordance with this statute, NHTSA promulgated 49 CFR part 543, which establishes the process through which manufacturers may seek an exemption from the theft prevention standard.

49 CFR 543.5 provides general submission requirements for petitions and states that each manufacturer may petition NHTSA for an exemption of one vehicle line per model year. Among other requirements, manufacturers must identify whether the exemption is sought under section 543.6 or section 543.7. Under section 543.6, a manufacturer may request an exemption by providing specific information about the antitheft device, its capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements. Section 543.7 permits a manufacturer to request an exemption under a more streamlined process if the vehicle line is equipped with an antitheft device (an ''immobilizer'') as standard equipment that complies with one of the standards specified in that section.[1]

Section 543.8 establishes requirements for processing petitions for exemption from the theft prevention standard. As stated in section 543.8(a), NHTSA processes any complete exemption petition. If NHTSA receives an incomplete petition, NHTSA will notify the petitioner of the deficiencies. Once NHTSA receives a complete petition the agency will process it and, in accordance with section 543.8(b), will grant the petition if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541.

Section 543.8(c) requires NHTSA to issue its decision either to grant or to deny an exemption petition not later than 120 days after the date on which a complete petition is filed. If NHTSA does not make a decision within the 120-day period, the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the petition for the subsequent model year.[2] Exemptions granted under part 543 apply only to the vehicle line or lines that are subject to the grant and that are equipped with the antitheft device on which the line's exemption was based, and are effective for the model year beginning after the model year in which NHTSA issues the notice of exemption, unless the notice of exemption specifies a later year.

Sections 543.8(f) and (g) apply to the manner in which NHTSA's decisions on petitions are to be made known. Under section 543.8(f), if the petition is sought under section 543.6, NHTSA publishes a notice of its decision to grant or deny the exemption petition in the **Federal Register** and notifies the petitioner in writing. Under section 543.8(g), if the petition is sought under section 543.7, NHTSA notifies the petitioner in writing of the agency's decision to grant or deny the exemption petition.

This grant of petition for exemption considers Mazda Motor Corporation's (Mazda) petition for its confidential vehicle line beginning in MY 2024.

I. Specific Petition Content Requirements Under 49 CFR 543.6

Pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention,* Mazda petitioned for an exemption for its specified vehicle line from the parts-marking requirements of the theft prevention standard, beginning in MY 2024. Mazda petitioned under 49 CFR 543.6, *Petition: Specific content requirements,* which, as described above, requires manufacturers to provide specific information about the antitheft device installed as standard equipment on all vehicles in the line for which an exemption is sought, the antitheft device's capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements.

More specifically, section 543.6(a)(1) requires petitions to include a statement that an antitheft device will be installed as standard equipment on all vehicles in the line for which the exemption is sought. Under section 543.6(a)(2), each petition must list each component in the antitheft system, and include a diagram showing the location of each of those components within the vehicle. As required by section 543.6(a)(3), each petition must include an explanation of the means and process by which the device is activated and functions, including any aspect of the device designed to: (1) facilitate or encourage its activation by motorists; (2) attract attention to the efforts of an unauthorized person to enter or move a vehicle by means other than a key; (3) prevent defeating or circumventing the device by an unauthorized person attempting to enter a vehicle by means other than a key; (4) prevent the operation of a vehicle which an unauthorized person has entered using means other than a key; and (5) ensure the reliability and durability of the device.[3]

In addition to providing information about the antitheft device and its functionality, petitioners must also submit the reasons for their belief that the antitheft device will be effective in reducing and deterring motor vehicle theft, including any theft data and other

[1] 49 CFR 543.7 specifies that the manufacturer must include a statement that their entire vehicle line is equipped with an immobilizer that meets one of the following standards:

(1) The performance criteria (subsections 8 through 21) of C.R.C, c. 1038.114, *Theft Protection and Rollaway Prevention (in effect March 30, 2011),* as excerpted in appendix A of [part 543];

(2) National Standard of Canada CAN/ULC–S338–98, *Automobile Theft Deterrent Equipment and Systems: Electronic Immobilization* (May 1998);

(3) United Nations Economic Commission for Europe (UN/ECE) Regulation No. 97 (ECE R97), *Uniform Provisions Concerning Approval of Vehicle Alarm System (VAS) and Motor Vehicles with Regard to Their Alarm System (AS)* in effect August 8, 2007; or

(4) UN/ECE Regulation No. 116 (ECE R116), *Uniform Technical Prescriptions Concerning the Protection of Motor Vehicles Against Unauthorized Use* in effect on February 10, 2009.

[2] 49 U.S.C. 33106(d).

[3] 49 CFR 543.6(a)(3).

data that are available to the petitioner and form a basis for that belief,[4] and the reasons for their belief that the agency should determine that the antitheft device is likely to be as effective as compliance with the parts-marking requirements of part 541 in reducing and deterring motor vehicle theft. In support of this belief, the petitioners should include any statistical data that are available to the petitioner and form the basis for the petitioner's belief that a line of passenger motor vehicles equipped with the antitheft device is likely to have a theft rate equal to or less than that of passenger motor vehicles of the same, or a similar, line which have parts marked in compliance with part 541.[5]

The following sections describe Mazda's petition information provided pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention.* To the extent that specific information in Mazda's petition is subject to a properly filed confidentiality request, that information was not disclosed as part of this notice.[6]

II. Mazda's Petition for Exemption

In a petition dated May 19, 2022, Mazda requested an exemption from the parts-marking requirements of the theft prevention standard for its confidential vehicle line beginning with MY 2024.

In its petition, Mazda provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the confidential vehicle line. Mazda stated that its MY 2024 confidential vehicle line will be installed with a passive, transponder based, electronic engine immobilizer antitheft device as standard equipment. Key components of its antitheft device will include a powertrain control module (PCM), immobilizer control module, security indicator light, coil antenna, transmitter with transponder key (transponder key), low frequency (LF) antenna, radio frequency (RF) receiver and a low frequency unit (LFU). The device will not provide any visible or audible indication of unauthorized vehicle entry (*i.e.,* flashing lights or horn alarm) as standard equipment; however, Mazda stated that its device will incorporate a security indicator light which will provide a visual confirmation on the protection status of the antitheft device.

Pursuant to section 543.6(a)(3), Mazda explained that there are two methods of initiating the antitheft device operation process. Specifically, Mazda stated that the immobilizer system monitors two codes: (1) the transponder code, which the immobilizer control module checks with the transponder located in the transmitter; and (2) the immobilizer code, which the immobilizer control module checks with the powertrain's electronic control module. Mazda also stated that there are two means of checking the transponder code: (1) when the immobilizer control module communicates with the transmitter which includes a transponder by LF antenna and receives a reply of transmitter in the RF receiver; and (2) when the immobilizer control module communicates with the transponder by coil antenna which is located in the push button start. If the transponder code matches with the immobilizer control module by either method mentioned above, and the ignition is turned to the ON position, the immobilizer control module checks the powertrain's electronic control module with immobilizer code. Mazda further stated that the vehicle's engine can only be started if the immobilizer code matches the code previously programmed into the immobilizer control module. If the immobilizer code does not match, the engine will be disabled. Communications between the immobilizer system control function and the powertrain's electronic control module are encrypted. Mazda also stated that there are more than 15×10^6 different transponder codes, and each transponder is hard coded with a unique code at the time of manufacture.

As required in section 543.6(a)(3)(v), Mazda provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Mazda conducted tests based on its own specified standards. Mazda provided a detailed list of the tests conducted (*i.e.,* low/high temperature exposure operation, high temperature endurance, thermal cycling, thermal shock resistance, thermal shock endurance, humidity temperature cycling, high temperature and humidity endurance, water, dust, vibration, connector and lead/lock strength, chemical resistance, electromagnetic field, power line variations, DC stresses, electrostatic discharge and push button start strength) and stated that it believes the device is reliable and durable since it complied with its own specified requirements for each test. Additionally, Mazda stated that its device is extremely reliable and durable because it is computer-based and does not rely on any mechanical or moving parts. Mazda further stated that any attempt to slam-pull its vehicle's ignition will have no effect on a thief's ability to start the vehicle without the correct code being transmitted to the electronic control modules.

Mazda provided data from the Highway Loss Data Institute (HLDI), National Crime Information Center (NCIC), and Insurance Institute for Highway Safety (IIHS) on the effectiveness of other similar antitheft devices installed on vehicle lines in support of its belief that its device will be at least as effective as those comparable devices. Specifically, Mazda stated that its device was installed on certain MY 1996 Ford vehicles as standard equipment, (*i.e.,* all Ford Mustang GT and Cobra models, Ford Taurus LX, and SHO models and Ford Sable LS models). In MY 1997, Mazda installed its immobilizer device on the entire Ford Mustang vehicle line as standard equipment. When comparing 1995 model year Mustang vehicle thefts (without immobilizers) with MY 1997 Mustang vehicle thefts (with immobilizers), Mazda referenced the National Crime Information Center's (NCIC) theft information which showed that there was a 70% reduction in theft experienced when comparing MY 1997 Mustang vehicle thefts (with immobilizers) to MY 1995 Mustang vehicle thefts (without immobilizers). Mazda recognized that NHTSA requested data for vehicle sets that are as similar as possible to the vehicle for which the petition is written;[7] however, Mazda stated that there is no comparable data for Mazda's SUV before and after the implementation of an immobilizer system, because all of Mazda's similar vehicles have been equipped with a standard immobilizer from the onset of manufacture. In light of these considerations, Mazda stated that the NCIC and HLDI data provided supported its belief that the immobilizer system described in its petition will prove to be as, if not more effective, than the parts marking requirements of part 541 in reducing vehicle theft.

III. Decision To Grant the Petition

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.8(b), the agency grants a petition for exemption from the parts-marking requirements of part 541, either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541.

[4] 49 CFR 543.6(a)(4).

[5] 49 CFR 543.6(a)(5).

[6] 49 CFR 512.20(a).

[7] See 85 FR 55368 (Sep. 8, 2020).

NHTSA finds that Mazda has provided adequate reasons for its belief that the antitheft device for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard. This conclusion is based on the information Mazda provided about its antitheft device. NHTSA believes, based on Mazda's supporting evidence, that the antitheft device described for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.

The agency concludes that Mazda's antitheft device will provide four types of performance features listed in section 543.6(a)(3): promoting activation; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the theft prevention standard for a given model year. 49 CFR 543.8(f) contains publication requirements incident to the disposition of all part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the theft prevention standard.

If Mazda decides not to use the exemption for its requested vehicle line, the manufacturer must formally notify the agency. If such a decision is made, the line must be fully marked as required by 49 CFR 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if a manufacturer to which an exemption has been granted wishes in the future to modify the device on which the exemption is based, the company may have to submit a petition to modify the exemption. Section 543.8(d) states that a part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, section 543.10(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in the exemption.'' [8]

For the foregoing reasons, the agency hereby announces a grant in full of Mazda's petition for exemption for the confidential vehicle line from the parts-marking requirements of 49 CFR part 541, beginning with its MY 2024 vehicles.

Issued under authority delegated in 49 CFR 1.95, 501.5 and 501.8.

Jane H. Doherty,

Director, Office of International Policy, Fuel Economy & Consumer Standards.

[FR Doc. 2022–17105 Filed 8–9–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2019–0124; Notice 2]

North America Subaru, Inc., Denial of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition.

SUMMARY: North America Subaru, Inc., (NASI) on behalf of Subaru Corporation and Subaru of America, Inc. (Subaru) has determined that certain model year (MY) 2016–2020 Subaru Impreza motor vehicles do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, Reflective Devices, and Associated Equipment.* Subaru filed a noncompliance report dated October 10, 2019. NASI, on behalf of Subaru, petitioned NHTSA on October 23, 2019, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces and explains the denial of NASI's petition.

FOR FURTHER INFORMATION CONTACT: Leroy Angeles, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), (202) 366–5304, *Leroy.Angeles@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Overview

NASI has determined that certain MY 2016–2020 Subaru Impreza motor vehicles do not fully comply with S8.1.11 and S10.15.6 of FMVSS No. 108, *Lamps, Reflective Devices, and Associated Equipment* (49 CFR 571.108). Subaru filed a noncompliance report dated October 10, 2019, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* NASI petitioned NHTSA on October 23, 2019, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

Notice of receipt of NASI's petition was published with a 30-day public comment period, in the **Federal Register** (85 FR 39037, June 29, 2020). One comment was received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2019–0124.''

II. Vehicles Involved

Approximately 63,697 MY 2016–2020 Subaru Impreza 4 door and approximately 124,703 Subaru Impreza Station wagon vehicles, totaling 188,400 motor vehicles manufactured between September 23, 2016, and August 7, 2019, are potentially involved.

III. Noncompliance

NASI explains that there are two separate noncompliances associated with the subject vehicles' front combination lamps. First, the front combination lamps contain lower beam headlamps that do not meet the requirements of paragraph S10.15.6, and second, the front combination lamps contain reflex reflectors that do not meet the requirements of paragraph S8.1.11 of FMVSS No. 108. Specifically, when tested, the lower beam in two of four front combination lamps (samples: LH1 and LH4) and the reflex reflector in four of four front combination lamps (samples LH1, LH2, LH3 and LH4) failed to comply at certain test points.

IV. Rule Requirements

S8.1.11 and S10.15.6 of FMVSS No. 108 include the requirements relevant to this petition. 49 CFR 571.108, S8.1.11 requires each reflex reflector be designed to conform to the photometry requirements of Table XVI–a when

[8] The agency wishes to minimize the administrative burden that section 543.10(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be de minimis. Therefore, NHTSA suggests that if a manufacturer with an exemption contemplates making any changes, the effects of which might be characterized as de minimis, it should consult the agency before preparing and submitting a petition to modify.

tested according to the procedure of S14.2.3. 49 CFR 571.08, S10.15.6 requires each replaceable bulb headlamp be designed to conform to the photometry requirements of Table XIX for lower beam as specified in Table II–d for the specific headlamp unit and aiming method, when tested according to the procedure of S14.2.5 using any replaceable light source designated for use in the system under test.

V. Summary of NASI's Petition

The following views and arguments presented in this section, ''V. Summary of NASI's Petition,'' are the views and arguments provided by NASI and do not reflect the views of the Agency.

NASI described the subject noncompliance and contended that the noncompliance is inconsequential as it relates to motor vehicle safety.

1. NASI submitted that the nonconformance relating to side reflex reflector photometry is inconsequential as it relates to motor vehicle safety for the following reasons:

a. Real-world testing conducted by NASI showed that noncompliant and compliant reflex reflectors are equally detectable in real-world conditions. NASI included an overview of cognitive performance testing of the compliant and noncompliant reflex reflectors with its petition which can be found in full on the FDMS website.[1] The cognitive performance test set-up simulated a condition typical of a vehicle approaching an unlit, perpendicular vehicle stalled in the driving lane. This test condition simulates a real-world condition where side reflex reflectors would support improved visibility of that vehicle. The test results show that, with respect to light reflectance and their ability to be detected, there is no noticeable difference observable between the fully compliant reflex reflector and the reflex reflector that marginally fails to comply at select test points.

b. At a majority of the test points where the tested reflex reflectors were found to have measured intensities below the required minimum values, the measured values were generally only slightly less than the required minimum. For two of the four lamp assemblies tested, there was one point (point HV) where measured values slightly exceeded the 25% threshold cited by NHTSA and others in the past as being the threshold at which the difference between two lamp intensities of less than 25% cannot be detected reliably by most drivers.[2] The two measured values were below the required minimums by 26.9% (sample LH1) and 27.7% (sample LH4). NASI noted that, on average, for the four samples tested by Calcoast, the HV test point was only 24.8% below the required minimum. We also note, as mentioned above, that the cognitive performance testing conducted by NASI found there to be no noticeable differences in detectability for the compliant and noncompliant reflex reflectors in question.

c. For a dynamic situation, light reflecting at a particular test point will be observed for only a short period of time. Compared to a light source that is constantly illuminated, the intensity originating from a reflex reflector is more fleeting to an observer. Reflex reflector intensity varies significantly depending on the angle of the driver's eyes to the reflector's central axis. Larger angles mean less light will be seen from the reflex reflector. Smaller angles mean more light will be seen from the reflex reflector. As a result, a nonconformity at a given test point for a reflex reflector will generally have a minimal impact on detectability. Thus, minor nonconformances at any one test point should be inconsequential with respect to safety risk.

d. NASI contended that it has been recognized by NHTSA in the past that it is inherently difficult to manufacture all lamps[3] to comply with all test points and that random failures do occur. FMVSS No. 108 requires lighting equipment be designed to conform to relevant requirements as opposed to simply comply with relevant requirements. NASI stated that according to NHTSA,[4] occasional random noncompliances are to be expected in this very complicated design and manufacturing process and it is for this reason that the ''designed to comply''[5] provision is contained in the lighting standard. *See* commentary from the NPRM[6] in which NHTSA proposed to amend FMVSS No. 108 to permit the certification of adaptive driving beam headlighting systems. In that notice, the Agency noted that, historically, there has never been an absolute requirement that every motor vehicle lighting device meets every single photometric test point to comply with FMVSS No. 108.

e. NASI stated that NHTSA has previously granted Subaru[7] and General Motors[8] petitions for inconsequentiality involving side reflex reflectors which were determined to be nonconforming at select test points by varying degrees.

f. NASI claimed that it is not aware of any field or customer complaints related to the performance of the side reflex reflectors contained the subject front combination lamps, nor has it been made aware of any accidents or injuries that have occurred relating to the performance of these lamp assemblies.

2. NASI submitted that the nonconforming condition relating to lower beam photometry is inconsequential as it relates to motor vehicle safety for the following reasons:

a. In compliance testing conducted by CALCOAST–ITL on behalf of NHTSA,[9] two of four front combination lamps tested (samples LH1 and LH4) failed to comply with certain low beam photometry requirements in S10.15.6.

i. Sample LH1:

- Front combination lamp sample LH1 photometry was measured at twenty-four test points. At two of the twenty-four test points, sample LH1 exceeded the maximum allowable luminous intensity values by small amounts (11.4% and 4.7%). At one of the twenty-four test points, sample LH1 was below the minimum acceptable luminous intensity value by 13.0%.
- At 21 of 24 test points, sample LH1 complied with the specified luminous intensity values listed in Table XIX–a (LB2V).

ii. Sample LH4

- Front combination lamp sample LH4 photometry was measured at 24 test points. At two of the twenty-four test points, the sample LH4 exceeded the maximum allowable luminous intensity values by small amounts (16.8% and 19.4%).

[1] *https://www.regulations.gov/document/NHTSA-2019-0124-0001.*

[2] *See* DOT report, *Driver Perception of Just Noticeable Differences of Automotive Signal Lamp Intensities,* DOT HS 808 209, September 1994. *https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB95206306.xhtml.*

[3] Reflex reflectors are considered reflective devices and not lamps. FMVSS No. 108 defines reflex reflectors as ''devices used on vehicles to give an indication to approaching drivers using reflected light from the lamps of the approaching vehicle.''

[4] *See Nissan Motor Corporation, U.S.A.; Denial of Application for Decision of Inconsequential Noncompliance;* 62 FR 63416, November 28, 1997.

[5] Specific to reflex reflectors and the lower beam, the regulatory text uses the phrase ''designed to conform.'' This phrase will be used throughout the analysis section for clarity.

[6] *See Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices, and Associated Equipment;* 83 FR 51766, October 12, 2018.

[7] *See Subaru of America; Grant of Petition for Determination of Inconsequential Noncompliance;* 56 FR 59971, November 26, 1991.

[8] *See General Motors Corporation; Grant of Petition for Determination of Inconsequential Noncompliance;* 57 FR 45866, October 5, 1992.

[9] *See* NHTSA Report No. 108–CAN–19–002. *https://static.nhtsa.gov/odi/ctr/9999/TRTR-646051-2019-001.pdf.*

• At 22 of 24 test points, sample LH4 complied with the specified luminous intensity values listed in Table XIX–a (LB2V).

iii. For both samples LH1 and LH4, test points at which the maximum allowable luminous intensity values were exceeded at test points 1.0 degree and 0.5 degrees up from the horizontal, respectively. These test points, which were taken in the range of 1.5 degrees to 9.9 degrees left of center, are in place to ensure that glare is minimized to oncoming drivers. In the UMTRI report entitled ''Just Noticeable Differences for Low-Beam Headlamp Intensities'' (UMTRl–97–4), testing was conducted to evaluate ''just noticeable differences'' or JNDs for glare intensities of oncoming low-beam headlamps. Specifically, UMTRI looked at whether the 25% rule established by NHTSA for signal lamps would be applicable for the range of intensities relevant to low-beam headlamps. Based on the testing conducted by UMTRI using low-beam headlamps, UMTRI concluded that applying the 25% limit for inconsequential noncompliance to a photometric test point that specifies a maximum for glare protection would be appropriate. Given the UMTRI conclusion, it believes that the small exceedances in maximum intensities for these two test points are inconsequential to safety.

iv. For sample LH1, test point 4.0D 20.0R was the third point which was noncompliant per the measurements taken. This test point measures light intensity down and to the right (4 degrees below the horizontal and 20 degrees to the right of center). The minimum intensity value ensures adequate light down and far right (*e.g.,* sidewalk to the right of the vehicle). Sample LH1's measured light intensity was 13% less than the required value.

Of the four samples tested by Calcoast, only one sample was noncompliant at this test point. This degree of nonconformity was minimal (13% below the required value). When the other three samples were tested, the measured intensities at this test point complied with margins of 47.2%, 27.8% and 2.8%.

For sample LH1, a point within the Zone 10U–90U/90L–90R at 10.00U–7.3R exceeded the maximum permissible intensity threshold by 8.7%. The maximum allowable intensity of 125 candelas in this zone was established to reduce the amount of glare to the driver of the car with the subject headlamp in driving conditions involving poor weather (rain, fog, snow, etc.). The consequence of one of four samples having a measurement of 8.7% above the maximum allowable value is inconsequential given the exceedance is far less than the 25% just noticeable difference.

As discussed previously in its petition, NASI stated that NHTSA has recognized in the past that it is inherently difficult to manufacture all lamps to comply with all test points and that random failures do occur. FMVSS No. 108 requires lighting equipment to be designed to conform to relevant requirements as opposed to simply comply with relevant requirements. Occasional random noncompliances are to be expected.[10] This is why there has never been an absolute requirement that every motor vehicle lighting device meets every single photometric test point to comply with FMVSS No. 108.[11]

Based on the data before it, NASI stated that it believes that the light intensity measured at test point 4.0D 20.0R for one of four samples tested is inconsequential to safety.

b. NASI claimed that it is not aware of any field or customer complaints related to the low-beam performance of the subject front combination lamps, nor has it been made aware of any accidents or injuries that have occurred relating to the performance of these lamp assemblies.

NASI concluded by reiterating that the subject noncompliance is inconsequential as it relates to motor vehicle safety and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

VI. Public Comment

NHTSA received one comment from the public.[12] The commenter stated a belief that NASI provided substantial evidence in support of its position, while also noting an inability to judge the merits of the petition. While the Agency appreciates the commenter's view on this issue, NHTSA finds that the information submitted by NASI does not satisfy its burden of persuasion as discussed below.

VII. NHTSA's Analysis

A. General Principles

The burden of establishing the inconsequentiality of a failure to comply with a *performance requirement* in a standard—as opposed to a *labeling requirement with no performance implications*—is more substantial and difficult to meet. Accordingly, the Agency has not found many such noncompliances inconsequential.[13]

An important issue to consider in determining inconsequentiality is the safety risk to individuals who experience the type of event against which the recall would otherwise protect.[14] The Safety Act is preventive, and manufacturers cannot and should not wait for deaths or injuries to occur in their vehicles before they carry out a recall. *See, e.g., United States* v. *Gen. Motors Corp.,* 565 F.2d 754, 759 (D.C. Cir. 1977). Indeed, the very purpose of a recall is to protect individuals from risk. *See id.* In general, NHTSA does not consider the absence of complaints or injuries to show that the issue is inconsequential to safety. ''Most importantly, the absence of a complaint does not mean there have not been any safety issues, nor does it mean that there will not be safety issues in the future.'' [15] ''[T]he fact that in past reported cases good luck and swift reaction have prevented many serious injuries does not mean that good luck will continue to work.'' [16]

B. NHTSA's Response to NASI's Petition

FMVSS No. 108 establishes the minimum level of performance for lighting and reflective equipment. The petitioner, not NHTSA, has the burden to demonstrate that a noncompliance with the FMVSS is inconsequential to safety. In the past, the Agency has only determined that a noncompliance with photometric requirements to be inconsequential to safety in very limited

[10] *See Nissan Motor Corporation, U.S.A.; Denial of Application for Decision of Inconsequential Noncompliance;* 62 FR 63416, November 28, 1997.

[11] *See Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices, and Associated Equipment;* 83 FR 51766, October 12, 2018.

[12] Docket No. NHTSA–2019–0124–0003.

[13] *Cf. Gen. Motors Corporation; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19899 (Apr. 14, 2004) (citing prior cases where noncompliance was expected to be imperceptible, or nearly so, to vehicle occupants or approaching drivers).

[14] *See Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

[15] *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21666 (Apr. 12, 2016).

[16] *United States* v. *Gen. Motors Corp.,* 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it ''results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future'').

circumstances, such as when we have determined the brightness differential would not be noticeable to an observer.

NHTSA's analysis will consider each of the two noncompliances.

The first noncompliance to be considered, 49 CFR 571.108, S8.1.11, concerns the reflex reflector. The purpose of the reflex reflectors, among other things, is to provide conspicuity to vehicles that are not in operation at night. There is a safety need to provide ample conspicuity to vehicles in order to reduce the risk of motor vehicle crashes.

NASI claimed the real-world testing it conducted showed that noncompliant and compliant reflex reflectors are equally detectable in real-world conditions. NHTSA disagrees. In this case, NASI's testing did not have human participants but instead a camera was used to check visibility of a reflex reflector. NHTSA reviewed the submitted study, and determined that there is a clear difference between the compliant and non-compliant reflex reflector. Further, NHTSA's test data along with NASI's in-house failed sample confirms the failures are comparable to each other. In addition, the position of the surrogate vehicle was for only one position and was directly in front of the stimulus vehicle.

NASI claimed that a nonconformity at a given test point for a reflex reflector will generally have a minimal impact on detectability and therefore concluded that minor nonconformances at any one test point should be inconsequential with respect to safety risk. NHTSA disagrees, especially considering that 3 of the 5 required test points were not met. Even if light reflecting at a particular test point will be observed for only a short period of time, since there is a drop in performance over several observable angles, we believe that the detectability of this reflex reflector may be impacted when compared to a compliant reflex reflector. Therefore, we do not agree with NASI's conclusion.

We do not agree that the study referenced by NASI (DOT HS 808 209) adequately supports any conclusion that a 25% deviation from the photometric requirement for a reflex reflector is inconsequential. First, this study does not apply to reflex reflectors. Second, the performance requirements for reflex reflectors are measured in (cd/incident ft-c) or (mcd/lux), whereas the performance requirements for signal lighting assessed in the study are measured in candela (cd). Absent compelling evidence, which NASI has not supplied, the Agency does not believe there is any basis for applying the conclusions of a study limited to one type of lighting equipment and criteria to another form of equipment evaluated by different criteria.

NASI also cites two past petition grants predating DOT HS 808 209; one for Subaru [17] and one for General Motors,[18] where NHTSA concurred with the proposition that a 25% deviation in reflector performance is imperceptible. Since evaluating Subaru's petition almost thirty years ago, NHTSA's line of reasoning on this subject has evolved. In the previous Subaru petition, NHTSA applied rationale related to tail lamps to reflex reflectors. Today, as explained previously in this section, NHTSA recognizes that the photometry criteria evaluated for reflex reflectors is measured in (cd/incident ft-c) or (mcd/lux) whereas tail lamps are measured in candela (cd) and therefore it is not proper to apply the logic of the tail lamp analysis to reflex reflectors, despite the prior grant.[19]

Further, NHTSA does not find the decision issued in the General Motors petition as particularly applicable or persuasive. In that instance, General Motors determined that a noncompliance existed because the installation of an accessory front end cover available at its dealerships masked an existing compliant side marker to the extent that the vehicle with the cover installed did not meet Standard No. 108. Among other things, NHTSA's notice granting GM's petition observed that the Agency would not necessarily have considered the condition caused by the installation of the front-end cover as a non-compliance.

The second noncompliance pertains to the lower beam not meeting the photometric requirements of FMVSS No. 108, S10.15.6. The purpose of the lower beam, among other things, is to provide down-road illumination while not causing glare to other road users. There is an obvious safety need to minimize glare in order to reduce the risk of motor vehicle crashes.

NHTSA does not concur with the conclusion NASI drew from an UMTRI study [20] that exceeding maximum intensities is inconsequential to safety because NHTSA has no glare-specific study indicating that the level of ''glare'' involved here is safe and NASI's petition does not provide any other data establishing that the headlamp noncompliance here has no impact on safety. Furthermore, OVSC reviewed the compliance test data for the samples NHTSA tested and observed that all four samples showed the lower beam to consistently and significantly exceed the maximum photometric requirement at similar test points, prior to a 0.25-degree re-aim allowed by S14.2.5.5 of FMVSS No. 108 for headlamp photometric measurement of all headlamps except a Type F upper beam unit not equipped with a vehicle headlamp aiming device (VHAD). The 0.25-degree re-aim procedure affords manufacturers flexibility in meeting the photometric requirements to allow for variations in readings between laboratories. Given this flexibility is already incorporated into the procedure, NHTSA does not agree that failure to meet the requirements after the re-aim is inconsequential to safety.

With respect to the ''design to conform'' argument that NASI applied to both the lower beam and the reflex reflector, NASI claimed that ''occasional random noncompliances are to be expected'' and that the ''designed to conform'' provision contained in the lighting standard indicates that the Agency does not demand a higher standard of compliance beyond the manufacturer's design intent. NASI cited commentary from NHTSA's NPRM related to amending FMVSS No. 108 to permit the certification of adaptive driving beam (ADB) headlighting systems. However, NHTSA's Final Rule on ADB noted that the ''designed to conform'' language was a product of the technology available back in 1967, and that NHTSA may not come to the same conclusion if it were to revisit the issue today, in light of the fact that lighting equipment design, technology, and manufacturing have evolved and advanced since the late 1960's.[21]

Additionally, NHTSA also finds that, without consideration of the claim that items that must meet FMVSS No. 108 need only be designed to conform, that

[17] *See Subaru of America; Grant of Petition for Determination of Inconsequential Noncompliance;* 56 FR 59971, November 26, 1991.

[18] *See General Motors Corporation; Grant of Petition for Determination of Inconsequential Noncompliance;* 57 FR 45866, October 5, 1992.

[19] NHTSA acknowledges that a petition for failure to meet reflex reflector (luminosity) was granted as recently as 2020; however, the facts of that petition are substantially different in that the actual measured noncompliance was marginal (one test point having a value .05% below the requirement) and the bulk of rationale was based on a theoretical worst case analysis. *See Toyota Motor North America, Inc., Grant of Petition for Decision of Inconsequential Noncompliance;* 85 FR 39679, July 1, 2020.

[20] *See Just Noticeable Differences for Low-Beam Headlamp Intensities* (Sayer, Flannagan, Sivak, Kojima, and Flannagan), Report No. UMTRI–97–4, February 1997.

[21] *Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices, and Associated Equipment, Adaptive Driving Beam Headlamps,* 87 FR 9916, 9940 n.92 February 22, 2022.

design intent is immaterial to the disposition of this petition. NASI's Part 573 filing states that the side reflex reflector production molds were damaged, and the lower beam reflector mold was worn and both conditions caused product performance issues. Therefore, whatever NASI's design intent may have been, the failure to conform in the instant case apparently stems from a systemic production problem that is wholly distinct from whether the components were ''designed to conform.''

NHTSA has consistently held that a lamp's failure to meet performance requirements will not constitute a compliance failure when such failures are random and occasional.[22] However, the test failures for two of the four lower beam functions that NHTSA tested, and four of the four side reflex reflectors that NHTSA tested occurred at around the same test points and photometric values. All of these failures were found to be within 1% to 10% of each other. These data support a pattern of performance that is neither random nor occasional. Based on the pattern of failure established with four samples tested, NHTSA finds that if more lamps were tested, more than an occasional number of failures would be obtained.

VIII. NHTSA's Decision

In consideration of the foregoing, NHTSA has decided that NASI has not met its burden of persuasion that the subject FMVSS No. 108 noncompliance is inconsequential to motor vehicle safety. Accordingly, NASI's petition is hereby denied and NASI is consequently obligated to provide notification of and free remedy for that noncompliance under 49 U.S.C. 30118 and 30120.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Anne L. Collins,

Associate Administrator for Enforcement.

[FR Doc. 2022–17130 Filed 8–9–22; 8:45 am]

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[22] *See Nissan Motor Corporation, U.S.A.; Denial of Application for Decision of Inconsequential Noncompliance;* 62 FR 63416, November 28, 1997.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption from the Federal Motor Vehicle Theft Prevention Standard; Ford Motor Company

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the Ford Motor Company (Ford) petition for exemption from the Federal Motor Vehicle Theft Prevention Standard (theft prevention standard) for its Bronco vehicle line beginning in model year (MY) 2023. The petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard. Ford also requested confidential treatment for specific information in its petition. Therefore, no confidential information provided for purposes of this notice has been disclosed.

DATES: The exemption granted by this notice is effective beginning with the 2023 model year.

FOR FURTHER INFORMATION CONTACT: Carlita Ballard, Office of International Policy, Fuel Economy, and Consumer Programs, NHTSA, West Building, W43–439, NRM–310, 1200 New Jersey Avenue SE, Washington, DC 20590. Ms. Ballard's phone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: Under 49 U.S.C. chapter 331, the Secretary of Transportation (and the National Highway Traffic Safety Administration (NHTSA) by delegation) is required to promulgate a theft prevention standard to provide for the identification of certain motor vehicles and their major replacement parts to impede motor vehicle theft. NHTSA promulgated regulations at 49 CFR part 541 (theft prevention standard) to require parts-marking for specified passenger motor vehicles and light trucks. Pursuant to 49 U.S.C. 33106, manufacturers that are subject to the parts-marking requirements may petition the Secretary of Transportation for an exemption for a line of passenger motor vehicles equipped with an antitheft device as standard equipment that the Secretary decides is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements. In accordance with this statute, NHTSA promulgated 49 CFR part 543, which establishes the process through which manufacturers may seek an exemption from the theft prevention standard.

49 CFR 543.5 provides general submission requirements for petitions and states that each manufacturer may petition NHTSA for an exemption of one vehicle line per model year. Among other requirements, manufacturers must identify whether the exemption is sought under section 543.6 or section 543.7. Under section 543.6, a manufacturer may request an exemption by providing specific information about the antitheft device, its capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements. Section 543.7 permits a manufacturer to request an exemption under a more streamlined process if the vehicle line is equipped with an antitheft device (an ''immobilizer'') as standard equipment that complies with one of the standards specified in that section.[1]

Section 543.8 establishes requirements for processing petitions for exemption from the theft prevention standard. As stated in section 543.8(a), NHTSA processes any complete exemption petition. If NHTSA receives an incomplete petition, NHTSA will notify the petitioner of the deficiencies. Once NHTSA receives a complete petition the agency will process it and, in accordance with section 543.8(b), will grant the petition if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541.

Section 543.8(c) requires NHTSA to issue its decision either to grant or to deny an exemption petition not later than 120 days after the date on which

[1] 49 CFR 543.7 specifies that the manufacturer must include a statement that their entire vehicle line is equipped with an immobilizer that meets one of the following standards:

(1) The performance criteria (subsection 8 through 21) of C.R.C, c. 1038.114, Theft Protection and Rollaway Prevention (in effect March 30, 2011), as excerpted in appendix A of [part 543];

(2) National Standard of Canada CAN/ULC–S338–98, Automobile Theft Deterrent Equipment and Systems: Electronic Immobilization (May 1998);

(3) United Nations Economic Commission for Europe (UN/ECE) Regulation No. 97 (ECE R97), Uniform Provisions Concerning Approval of Vehicle Alarm System (VAS) and Motor Vehicles with Regard to Their Alarm System (AS) in effect August 8, 2007; or

(4) UN/ECE Regulation No. 116 (ECE R116), Uniform Technical Prescriptions Concerning the Protection of Motor Vehicles Against Unauthorized Use in effect on February 10, 2009.

a complete petition is filed. If NHTSA does not make a decision within the 120-day period, the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the petition for the subsequent model year.[2] Exemptions granted under part 543 apply only to the vehicle line or lines that are subject to the grant and that are equipped with the antitheft device on which the line's exemption was based, and are effective for the model year beginning after the model year in which NHTSA issues the notice of exemption, unless the notice of exemption specifies a later year.

Sections 543.8(f) and (g) apply to the manner in which NHTSA's decisions on petitions are to be made known. Under section 543.8(f), if the petition is sought under section 543.6, NHTSA publishes a notice of its decision to grant or deny the exemption petition in the **Federal Register** and notifies the petitioner in writing. Under section 543.8(g), if the petition is sought under section 543.7, NHTSA notifies the petitioner in writing of the agency's decision to grant or deny the exemption petition.

This grant of petition for exemption considers Ford Motor Corporation's (Ford) petition for its Bronco vehicle line beginning in MY 2023.

I. Specific Petition Content Requirements Under 49 CFR 543.6

Pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention,* Ford petitioned for an exemption for its specified vehicle line from the parts-marking requirements of the theft prevention standard, beginning in MY 2023. Ford petitioned under 49 CFR 543.6, *Petition: Specific content requirements,* which, as described above, requires manufacturers to provide specific information about the antitheft device installed as standard equipment on all vehicles in the line for which an exemption is sought, the antitheft device's capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements.

More specifically, section 543.6(a)(1) requires petitions to include a statement that an antitheft device will be installed as standard equipment on all vehicles in the line for which the exemption is sought. Under section 543.6(a)(2), each petition must list each component in the antitheft system, and include a diagram showing the location of each of those components within the vehicle. As required by section 543.6(a)(3), each petition must include an explanation of the means and process by which the device is activated and functions, including any aspect of the device designed to: (1) facilitate or encourage its activation by motorists; (2) attract attention to the efforts of an unauthorized person to enter or move a vehicle by means other than a key; (3) prevent defeating or circumventing the device by an unauthorized person attempting to enter a vehicle by means other than a key; (4) prevent the operation of a vehicle which an unauthorized person has entered using means other than a key; and (5) ensure the reliability and durability of the device.[3]

In addition to providing information about the antitheft device and its functionality, petitioners must also submit the reasons for their belief that the antitheft device will be effective in reducing and deterring motor vehicle theft, including any theft data and other data that are available to the petitioner and form a basis for that belief,[4] and the reasons for their belief that the agency should determine that the antitheft device is likely to be as effective as compliance with the parts-marking requirements of part 541 in reducing and deterring motor vehicle theft. In support of this belief, the petitioners should include any statistical data that are available to the petitioner and form the basis for the petitioner's belief that a line of passenger motor vehicles equipped with the antitheft device is likely to have a theft rate equal to or less than that of passenger motor vehicles of the same, or a similar, line which have parts marked in compliance with part 541.[5]

The following sections describe Ford's petition information provided pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention.* To the extent that specific information in Ford's petition is subject to a properly filed confidentiality request, that information was not disclosed as part of this notice.[6]

II. Ford's Petition for Exemption

In a petition dated April 7, 2022, Ford requested an exemption from the parts-marking requirements of the theft prevention standard for its Bronco vehicle line beginning with MY 2023.

In its petition, Ford provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the Bronco vehicle line. Ford stated that its MY 2023 Bronco vehicle line will be installed with a passive, transponder based, electronic engine immobilizer antitheft device as standard equipment. Specifically, Ford stated that its vehicle line will be installed with the Intelligent Access with Push Button Start (IAwPB). Key components of the IAwPB device will include an Intelligent Access electronic Push-Button Start key fob, keyless ignition system, radio transceiver module, body control module (BCM), powertrain control module (PCM), and an anti-lock braking system module (ABS). Ford also stated that its vehicle line will be equipped with a hood release, counterfeit resistant VIN label, secondary VINs inscribed on the body and a cabin accessible with a valid keycode as standard antitheft features.

Ford further stated that its Bronco vehicle line will also be offered with a perimeter alarm system[7] as optional equipment which will activate a visible and audible alarm whenever unauthorized access is attempted. Some additional features of the antitheft device include: encrypted communication between the transponder, BCM control function and the PCM; ''virtually impossible'' key duplication; and shared security data between the body control module/remote function actuator and the powertrain control module. NHTSA has previously approved the IAwPB antitheft system as standard equipment for the Ford Bronco Sport vehicle line. The IAwPB system is described in the grant of petition for exemption published in the **Federal Register** on August 12, 2020.

Pursuant to section 543.6(a)(3), Ford explained that its system is automatically activated/armed when the ''StartStop'' button is pressed, shutting off the engine. Ford stated that the device is deactivated when a start sequence is completed and engine start is successful. Ford further stated that the vehicle engine can only be started when the key is present in the vehicle

[2] 49 U.S.C. 33106(d).

[3] 49 CFR 543.6(a)(3).

[4] 49 CFR 543.6(a)(4).

[5] 49 CFR 543.6(a)(5).

[6] 49 CFR 512.20(a).

[7] Ford also stated that it will offer an audible and visible alarm as optional equipment on its Bronco line. Per 49 U.S.C. 33106 (b), manufacturers may petition NHTSA for an exemption ''for a line of passenger motor vehicles equipped *as standard equipment* with an antitheft device that [NHTSA] decides is likely to be as effective in reducing and deterring motor vehicle theft as compliance with'' the Theft Prevention Standard (emphasis added). Per 49 U.S.C. 33106(a)(2), ''standard equipment'' means equipment already installed in a motor vehicle when it is delivered from the manufacturer and not an accessory or other item that the first purchaser customarily has the option to have installed. Therefore, for purposes of Ford's petition, NHTSA is only considering the device equipped on the vehicle as standard equipment.

and the ''StartStop'' button inside the vehicle is pressed. Ford stated that when the ''StartStop'' button is pressed, the transceiver module will read a key code and transmit an encrypted message to the control module to determine key validity and engine start by sending a separate encrypted message to the BCM and the PCM. The powertrain will function only if the key code matches the unique identification key code previously programmed into the BCM. Ford stated that the two modules must be matched together in order for the vehicle to start. If the codes do not match, the powertrain engine starter, spark, and fuel will be disabled. Ford further stated that any attempt to operate the vehicle without transmission of the correct code to the electronic control (*i.e.,* short circuiting the ''StartStop'' button) module will be ineffective.

As required in section 543.6(a)(3)(v), Ford provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Ford stated that it conducted tests on the antitheft device which complied with its own specific standards. Additionally, Ford stated that its antitheft device has no moving parts (*i.e.,* BCM, PCM, and electrical components) to perform system functions, which eliminate the possibility of physical damage or deterioration from normal use; and mechanically overriding the device to start the vehicle is also impossible. In further addressing the reliability and durability of its device, Ford stated that its Bronco vehicle line will also be equipped with several other standard antitheft features common to Ford vehicles, (*i.e.,* hood release located inside the vehicle, counterfeit resistant VIN labels, secondary VINs, and cabin accessibility only with the use of a valid key fob).

Ford stated that the antitheft system installed in its 2023 MY Ford Bronco vehicles is similar to the system that was offered in the 2021 MY Ford Bronco Sport vehicles equipped with the IAwPB. The Bronco Sport vehicle line was granted a parts-marking exemption by NHTSA (85 FR 48759, August 12, 2020) beginning with its MY 2021 vehicles.

Ford believes that the Ford Bronco would have a similar theft rate to the Ford Bronco Sport. Ford specifically stated that the Bronco Sport vehicle line is comparable with the Ford Bronco in vehicle segment, size and equipment and since the IAwPB system is the primary theft deterrent on Ford vehicles, Ford believes that the Ford Bronco will likely have a very low theft rate based on the comparable Ford Bronco Sport average theft rate of approximately 0.5/1000. Ford also stated that its Ford Bronco Sport reported theft rates (thefts per thousand vehicles) that are lower than the ''all vehicle theft rate'' in each calendar year published.

III. Decision To Grant the Petition

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.8(b), the agency grants a petition for exemption from the parts-marking requirements of part 541, either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541. The agency finds that Ford has provided adequate reasons for its belief that the antitheft device for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard. This conclusion is based on the information Ford provided about its antitheft device. NHTSA believes, based on Ford's supporting evidence, that the antitheft device described for its vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard.

The agency concludes that Ford's antitheft device will provide four types of performance features listed in section 543.6(a)(3): promoting activation; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the theft prevention standard for a given model year. 49 CFR 543.8(f) contains publication requirements incident to the disposition of all part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the theft prevention standard.

If Ford decides not to use the exemption for its requested vehicle line, the manufacturer must formally notify the agency. If such a decision is made, the line must be fully marked as required by 49 CFR 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Ford wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Section 543.8(d) states that a part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, section 543.10(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in the exemption.''

The agency wishes to minimize the administrative burden that section 543.10(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be de minimis. Therefore, NHTSA suggests that if Ford contemplates making any changes, the effects of which might be characterized as de minimis, it should consult the agency before preparing and submitting a petition to modify.

For the foregoing reasons, the agency hereby grants in full Ford's petition for exemption for the Bronco vehicle line from the parts-marking requirements of 49 CFR part 541, beginning with its MY 2023 vehicles.

Issued under authority delegated in 49 CFR 1.95, 501.5 and 501.8.

Jane H. Doherty,

Director, Office of International Policy, Fuel Economy & Consumer Standards.

[FR Doc. 2022–17106 Filed 8–9–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2022–0075]

Pipeline Safety: Request for Special Permit, Natural Gas Pipeline Company of America, LLC

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice.

SUMMARY: PHMSA is publishing this notice to solicit public comments on a request for special permit received from

the Natural Gas Pipeline Company of America, LLC (NGPL). The special permit request is seeking relief from compliance with certain requirements in the Federal pipeline safety regulations. At the conclusion of the 30-day comment period, PHMSA will review the comments received from this notice as part of its evaluation to grant or deny the special permit request.

DATES: Submit any comments regarding this special permit request by September 9, 2022.

ADDRESSES: Comments should reference the docket number for this special permit request and may be submitted in the following ways:

- *E-Gov Website: http://www.Regulations.gov.* This site allows the public to enter comments on any **Federal Register** notice issued by any agency.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number for the special permit request you are commenting on at the beginning of your comments. If you submit your comments by mail, please submit two (2) copies. To receive confirmation that PHMSA has received your comments, please include a self-addressed stamped postcard. Internet users may submit comments at *http://www.Regulations.gov.*

Note: There is a privacy statement published on *http://www.Regulations.gov.* Comments, including any personal information provided, are posted without changes or edits to *http://www.Regulations.gov.*

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 Code of Federal Regulations (CFR) 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Kay McIver, DOT, PHMSA–PHP–80, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT:

General: Ms. Kay McIver by telephone at 202–366–0113, or by email at *kay.mciver@dot.gov.*

Technical: Mr. Steve Nanney by telephone at 713–272–2855, or by email at *steve.nanney@dot.gov.*

SUPPLEMENTARY INFORMATION: PHMSA received a special permit request from NGPL, a subsidiary of Kinder Morgan, Inc., on May 9, 2022, seeking a waiver from the requirements of 49 CFR 192.611(a) and (d): Change in class location: Confirmation or revision of maximum allowable operating pressure, and 49 CFR 192.619(a): Maximum allowable operating pressure: Steel or plastic pipelines.

This special permit is being requested in lieu of pipe replacement, pressure reduction, or new pressure tests for 14 gas transmission pipeline segments totaling 44,905.02 feet (approximately 8.505 miles) of 30-inch diameter pipe on the Louisiana Line #2 Pipeline (Pipeline) located in Montgomery and Liberty Counties, Texas.

The proposed special permit will allow NGPL to operate the Pipeline with original Class 1 pipe in Class 3 locations and to uprate the Pipeline from a current 936 pounds per square inch gauge (psig) maximum allowable operating pressure (MAOP) to a 1,100 psig MAOP. The MAOP uprate is being requested for additional gas flow capacity through the Pipeline. Prior to a 2007 MAOP reduction due to Class 1 to Class 3 location changes, the Pipeline operated at 1,100 psig. The Pipeline was constructed between 1974 and 1978.

The special permit request, proposed special permit with conditions, and draft environmental assessment (DEA) for the above listed NGPL pipeline segments are available for review and public comments in Docket No. PHMSA–2022–0075. PHMSA invites interested persons to review and submit comments on the special permit request and DEA in the docket. Please include any comments on potential safety and environmental impacts that may result if the special permit is granted. Comments may include relevant data.

Before issuing a decision on the special permit request, PHMSA will evaluate all comments received on or before the comments closing date. Comments received after the closing date will be evaluated, if it is possible to do so without incurring additional expense or delay. PHMSA will consider each relevant comment it receives in making its decision to grant or deny this special permit request.

Issued in Washington, DC, on August 5, 2022, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2022–17133 Filed 8–9–22; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's List of Specially Designated Nationals and Blocked Persons (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions

Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On August 1, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810–AL–P

Entities

1. BLUE CACTUS HEAVY EQUIPMENT AND MACHINERY SPARE PARTS TRADING L.L.C. (Arabic: بلو كاكتوس لتجارة قطع غيار اللت و المعدات الثقيلة ش.ذ.م.م), (a.k.a. BLUE CACTUS HEAVY EQUIPMENT & MACHINERY SPARE PARTS TRADING L.L.C.), P.O. Box 126242, United Arab Emirates; Plot No. 117-635, Dubai, United Arab ; Emirates; Additional Sanctions Information - Subject to Secondary Sanctions Organization Established Date 13 Aug 2015; Commercial Registry Number 1185785 (United Arab Emirates); Registration Number 738453 (United Arab Emirates) [IRAN-EO13846] (Linked To: PERSIAN GULF PETROCHEMICAL INDUSTRY .). COMMERCIAL CO

   Designated pursuant to section 1(a)(iii)(A) of Executive Order 13846 of August 6, 2018, "Reimposing Certain Sanctions With Respect to Iran," 83 FR 38939, 3 CFR, 2019 Comp., p. 854 (E.O. 13846) for, on or after November 5, 2018, having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, PERSIAN GULF PETROCHEMICAL INDUSTRY COMMERCIAL CO.

2. FARWELL CANYON HK LIMITED, Mau Lam Comm Bldg, 16-18 Mau Lam Str Jordan K1, Hong Kong, China; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 25 Nov 2020; Registration Number 2996965 (Hong Kong) [IRAN-EO13846] (Linked To: PERSIAN GULF PETROCHEMICAL INDUSTRY COMMERCIAL CO.).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13846 for, on or after November 5, 2018, having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, PERSIAN GULF PETROCHEMICAL INDUSTRY COMMERCIAL CO.

3. PZNFR TRADING LIMITED (a.k.a. PZNFR TRADING SDN BHD), Room 023, 9/F Blk G Kwai Shing Ind Building (Stage 2), 42-46 Tai Lin Pai Road, Kwai Chung NT, Hong Kong, China; Retail Lot L3-1, Level 3, Gateway Klia 2, Kuala Lumpur International Airport 2, Sepang, Selangor Darul Ehsan 64000, Malaysia; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 07 Dec 2020; Registration Number 3000264 (Hong Kong) [IRAN-EO13846] (Linked To: PERSIAN GULF PETROCHEMICAL INDUSTRY COMMERCIAL CO.).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13846 for, on or after November 5, 2018, having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, PERSIAN GULF PETROCHEMICAL INDUSTRY COMMERCIAL CO.

4. SHEKUFEI INTERNATIONAL TRADING CO., LIMITED, Room 3224 Qinghai Building, Tiangqing Village, Tin Shui Wai Yuen Long District, Hong Kong, China; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 03 Jun 2021; Registration Number 3054573 (Hong Kong) [IRAN-EO13846] (Linked To: PERSIAN GULF PETROCHEMICAL INDUSTRY COMMERCIAL CO.).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13846 for, on or after November 5, 2018, having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, PERSIAN GULF PETROCHEMICAL INDUSTRY COMMERCIAL CO.

Dated: August 4, 2022.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–17148 Filed 8–9–22; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Wednesday, September 14, 2022.

FOR FURTHER INFORMATION CONTACT: Conchata Holloway at 1–888–912–1227 or 214–413–6550.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Wednesday, September 14, 2022, at 12:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Conchata Holloway. For more information, please contact Conchata Holloway at 1–888–912–1227 or 214–413–6550, or write TAP Office, 1114 Commerce St., MC 1005, Dallas, TX 75242 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: August 4, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–17094 Filed 8–9–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Improvements Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will still be held via teleconference.

DATES: The meeting will be held Thursday, September 8, 2022.

FOR FURTHER INFORMATION CONTACT: Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Improvements Project Committee will be held Thursday, September 8, 2022, at 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Matthew O'Sullivan. For more information please contact Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274, or write TAP Office, 1301 Clay Street, Oakland, CA 94612–5217 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: August 4, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–17092 Filed 8–9–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Lines Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Lines Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, September 13, 2022.

FOR FURTHER INFORMATION CONTACT: Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Lines Project Committee will be held Tuesday, September 13, 2022, at 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements

for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Rosalind Matherne. For more information, please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: August 4, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–17088 Filed 8–9–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, September 22, 2022.

FOR FURTHER INFORMATION CONTACT: Gilbert Martinez at 1–888–912–1227 or (737) 800–4060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Thursday, September 22, 2022, at 1:30 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. For more information, please contact Gilbert Martinez at 1–888–912–1227 or (737–800–4060), or write TAP Office 3651 S IH–35, STOP 1005 AUSC, Austin, TX 78741, or post comments to the website: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: August 4, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–17087 Filed 8–9–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Special Projects Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will still be held via teleconference.

DATES: The meeting will be held Wednesday, September 14, 2022.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1–888–912–1227 or 202–317–4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be held Wednesday, September 14, 2022, at 11:00 a.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Antoinette Ross. For more information please contact Antoinette Ross at 1–888–912–1227 or 202–317–4110, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: August 4, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–17086 Filed 8–9–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, September 13, 2022.

FOR FURTHER INFORMATION CONTACT: Robert Rosalia at 1–888–912–1227 or (718) 834–2203.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will be held Tuesday, September 13, 2022, at 12:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Robert Rosalia. For more information, please contact Robert Rosalia at 1–888–912–1227 or (718) 834–2203, or write TAP Office, 2 Metrotech Center, 100 Myrtle Avenue, Brooklyn, NY 11201 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: August 4, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–17095 Filed 8–9–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, September 13, 2022.

FOR FURTHER INFORMATION CONTACT: Fred Smith at 1–888–912–1227 or (202) 317–3087.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be held Tuesday, September 13, 2022, at 1:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Fred Smith. For more information, please contact Fred Smith at 1–888–912–1227 or (202) 317–3087, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.*

Dated: August 4, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–17093 Filed 8–9–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

United States Mint

Request for Citizens Coinage Advisory Committee Membership Applications

ACTION: Notice.

Pursuant to United States Code, Title 31, section 5135(b), the United States Mint is accepting applications for appointment to the Citizens Coinage Advisory Committee (CCAC) as the member specially qualified to serve on the CCAC by virtue of their experience in the *medallic arts or sculpture.* The CCAC was established to:

- Advise the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals produced by the United States Mint.
- Advise the Secretary of the Treasury with regard to the events, persons, or places that the CCAC recommends to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made.
- Make recommendations with respect to the mintage level for any commemorative coin recommended.

Total membership consists of 11 voting members appointed by the Secretary of the Treasury:

- One person specially qualified by virtue of his or her education, training, or experience as nationally or internationally recognized curator in the United States of a numismatic collection;
- One person specially qualified by virtue of his or her experience in the medallic arts or sculpture;
- One person specially qualified by virtue of his or her education, training, or experience in American history;
- One person specially qualified by virtue of his or her education, training, or experience in numismatics;
- Three persons who can represent the interests of the general public in the coinage of the United States; and
- Four persons appointed by the Secretary of the Treasury on the basis of the recommendations by the House and Senate leadership.

Members are appointed for a term of four years. No individual may be appointed to the CCAC while serving as an officer or employee of the Federal Government.

The CCAC is subject to the direction of the Secretary of the Treasury. Meetings of the CCAC are open to the public and are held approximately four to six times per year. The United States Mint is responsible for providing the necessary support, technical services, and advice to the CCAC. CCAC members are not paid for their time or services, but, consistent with Federal Travel Regulations, members are reimbursed for their travel and lodging expenses to attend meetings. Members are Special Government Employees and are subject to the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2653).

The United States Mint will review all submissions and will forward its recommendations to the Secretary of the Treasury for appointment consideration. Candidates should include specific skills, abilities, talents, and credentials to support their applications. The United States Mint is interested in candidates who, in addition to their experience in the medallic arts or sculpture, have demonstrated interest and a commitment to actively participate in meetings and activities, and a demonstrated understanding of the role of the CCAC and the obligations of a Special Government Employee; possess demonstrated leadership skills in their fields of expertise or discipline; possess a demonstrated desire for public service and have a history of honorable professional and personal conduct, as well as successful standing in their communities; and who are free of professional, political, or financial interests that could negatively affect their ability to provide impartial advice.

Application Deadline: 5:00 p.m. (EDT), September 2, 2022

Receipt of Applications: Any member of the public wishing to be considered for appointment to the CCAC should submit a resume and cover letter describing his or her reasons for seeking and qualifications for membership, by email to *info@ccac.gov,* Attn: Jennifer Warren. The deadline to email submissions is no later than 5:00 p.m. (EDT) on Friday, September 2, 2022.

FOR FURTHER INFORMATION CONTACT: Jennifer Warren, United States Mint Liaison to the CCAC; *jennifer.warren@usmint.treas.gov* or 202–354–7208.

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2022–17089 Filed 8–9–22; 8:45 am]

BILLING CODE 4810–37–P

DEPARTMENT OF THE TREASURY

United States Mint

Request for Citizens Coinage Advisory Committee Membership Applications

ACTION: Notice.

SUMMARY: The United States Mint is accepting applications for appointment to the Citizens Coinage Advisory Committee (CCAC) as a member who can represent the interests of the general public in the coinage of the United States.

DATES: The deadline to email submissions is no later than 5:00 p.m. (EDT) on Friday, September 2, 2022.

ADDRESSES: Any member of the public wishing to be considered for appointment to the CCAC should submit a resume and cover letter describing his or her reasons for seeking and qualifications for membership, by email to *info@ccac.gov,* Attn: Jennifer Warren.

FOR FURTHER INFORMATION CONTACT: Jennifer Warren, United States Mint Liaison to the CCAC; *jennifer.warren@usmint.treas.gov* or 202–354–7208.

SUPPLEMENTARY INFORMATION: The CCAC was established to:

- Advise the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals produced by the United States Mint.
- Advise the Secretary of the Treasury with regard to the events, persons, or places that the CCAC recommends to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made.

• Make recommendations with respect to the mintage level for any commemorative coin recommended.

Total membership consists of 11 voting members appointed by the Secretary of the Treasury:

• One person specially qualified by virtue of his or her education, training, or experience as nationally or internationally recognized curator in the United States of a numismatic collection;

• One person specially qualified by virtue of his or her experience in the medallic arts or sculpture;

• One person specially qualified by virtue of his or her education, training, or experience in American history;

• One person specially qualified by virtue of his or her education, training, or experience in numismatics;

• Three persons who can represent the interests of the general public in the coinage of the United States; and

• Four persons appointed by the Secretary of the Treasury on the basis of the recommendations by the House and Senate leadership.

Members are appointed for a term of four years. No individual may be appointed to the CCAC while serving as an officer or employee of the Federal Government.

The CCAC is subject to the direction of the Secretary of the Treasury. Meetings of the CCAC are open to the public and are held approximately four to six times per year. The United States Mint is responsible for providing the necessary support, technical services, and advice to the CCAC. CCAC members are not paid for their time or services, but, consistent with Federal Travel Regulations, members are reimbursed for their travel and lodging expenses to attend meetings. Members are Special Government Employees and are subject to the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2653).

The United States Mint will review all submissions and will forward its recommendations to the Secretary of the Treasury for appointment consideration. Candidates should include specific skills, abilities, talents, and credentials to support their applications. The United States Mint is interested in candidates who have demonstrated interest and a commitment to actively participate in meetings and activities, and a demonstrated understanding of the role of the CCAC and the obligations of a Special Government Employee; possess demonstrated leadership skills in their fields of expertise or discipline; possess a demonstrated desire for public service and have a history of honorable professional and personal conduct, as well as successful standing in their communities; and who are free of professional, political, or financial interests that could negatively affect their ability to provide impartial advice.

Authority: 31 U.S.C. 5135(b).

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2022–17108 Filed 8–9–22; 8:45 am]

BILLING CODE 4810–37–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; Matching Program

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice of a modified matching program.

SUMMARY: The Department of Veterans Affairs (VA) provides notice that it intends to conduct a recurring computer-matching program matching Social Security Administration (SSA) Master Beneficiary Records (MBRs) and the Master Files of Social Security Number (SSN) Holders and SSN Applications (Enumeration System) with VA pension, compensation, and dependency and indemnity compensation (DIC) records. The goal of this match is to identify beneficiaries, who are receiving VA benefits and SSA benefits or earned income, and to reduce or terminate VA benefits, if appropriate. The match will include records of current VA beneficiaries.

DATES: Comments on this matching program must be received no later than 30 days after date of publication in the **Federal Register**]. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the new agreement will become effective a minimum of 30 days after date of publication in the **Federal Register**. If VA receives public comments, VA shall review the comments to determine whether any changes to the notice are necessary. This matching program will be valid for 18 months from the effective date of this notice.

ADDRESSES: Comments may be submitted through *www.Regulations.gov* or mailed to VA Privacy Service, 810 Vermont Avenue NW, (005R1A), Washington, DC 20420. Comments should indicate that they are submitted in response to Verify Unearned Income Information (DIFSLA). Comments received will be available at *regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Victor Hall, (202) 461–9385, *victor.hall2@va.gov,* Pension and Fiduciary Service, Front Office, Pension and Fiduciary Service (21P), Department of Veterans Affairs, 810 Vermont Ave. NW, Washington, DC 20420, (202) 632–8863

SUPPLEMENTARY INFORMATION: VA will use this information to verify the income information submitted by beneficiaries in VA's needs-based benefit programs and adjust VA benefit payments as prescribed by law.

The legal authority to conduct this match is 38 U.S.C. 5106, which requires any Federal department or agency to provide VA such information as VA requests for the purposes of determining eligibility for benefits or verifying other information with respect to payment of benefits.

The VA records involved in the match are in ''Compensation, Pension and Education and Rehabilitation Records—VA (58 VA 21/22/28),'' a system of records which was first published at 41 FR 9294 (March 3, 1976), amended and republished in its entirety at 86 FR 61858(November 8, 2021). The SSA records consist of information from the system of records identified as the SSA MBR, 60–0090, and SSA Enumeration System, 60–0058.

In accordance with the Privacy Act, 5 U.S.C. 552a(o)(2) and (r), copies of the agreement are being sent to both Houses of Congress and to the Office of Management and Budget. This notice is provided in accordance with the provisions of Privacy Act of 1974 as amended by Public Law 100–503.

Participating Agencies: The Social Security Administration (SSA) and Department of Veterans Affairs (VA).

Authority for Conducting the Matching Program: 38 U.S.C 5106 and 38 CFR, chapter 1, part 4 authorize VA to enter into this CMA with SSA.

Purpose(s): To re-establish a CMA with SSA for determining eligibility to continue to receive benefits authorized by the Department of Veterans Affairs (VA).

Categories of Individuals: Veterans and beneficiaries who apply for VA income benefits.

Categories of Records: VA will provide SSA with an electronic file in a format defined by SSA that contains the necessary identifying information for applicable beneficiaries and their dependents. Each VA input file will contain the following variables:

1. Social Security Number for Primary Number Holder
2. Last Name
3. First Name

4. Middle Name/Initial
5. Date of Birth (MMDDCCYY)
6. Sex Code (Blank)
7. VA File Number
8. Agency Code ''VA''
9. Type of Benefit
10. Veteran with Spouse Indicator
11. Payee Number
12. Type of Record
13. Verified Payment Indicator
14. Verification Indicator
15. Processing Code ''212''
16. Verification Account Number (VAN)
17. Blanks, or Multiple Request Code.

SSA will match the file against the Enumeration System and MBR will generate an output file with information on the following variables for each of VA's records containing a verified SSN:

1. Verification Code
2. Death Indicator
3. Filler
4. Type of Benefit—Retirement (R), Disability (D) or Survivor (S)
5. MCB (Monthly Benefit Credited)
6. MBP (Monthly Benefit Payment)
7. Medicare Deduction (SMI–B)
8. Effective Date of Monthly Social Security Payment ''CCYYMM''
9. LAF Code (D = Deferred/withheld money), (E = Monies paid through Railroad Board), (C = Current Pay)
10. Type of Benefit—Retirement (R), Disability (D) or Survivor (S)
11. MCB (Monthly Benefit Credited)
12. MBP (Monthly Benefit Payment)
13. Medicare Deduction (SMI–B)
14. Effective Date of Monthly Social Security Payment ''CCYYMM''
15. LAF Code (D = Deferred/withheld money), (E = Monies paid through Railroad Board), (C = Current Pay)
16. Type of Benefit—Retirement (R), Disability (D) or Survivor (S)
17. MCB (Monthly Benefit Credited)
18. MBP (Monthly Benefit Payment)
19. Medicare Deduction (SMI–B)
20. Effective Date of Monthly Social Security Payment ''CCYYMM''
21. LAF Code (D = Deferred/withheld money), (E = Monies paid through Railroad Board), (C = Current Pay)
22. Filler

''Some terms are repeated.

SYSTEM(S) OF RECORDS: SSA will disclose the necessary benefit information electronically from the files of the MBR, system of records number 60–0090, last fully published at 71 FR 1826 (January 11, 2006), amended at 72 FR 69723 (December 10, 2007), and at 78 FR 40542 (July 5, 2013), 83 FR 31250–31251 (July 3, 2018) and 83 FR 54969 (November 1, 2018). SSA will disclose SSN verification information from the Enumeration System, system of records number 60–0058, last fully published at 75 FR 82121 (December 29, 2010), amended at 78 FR 40542 (July 5, 2013), and at 79 FR 8780 (February 13, 2014), 83 FR 31250–31251 (July 3, 2018), and 83 FR 54969 (November 1, 2018).

VA records involved in this match are in ''VA Compensation, Pension, Education, and Vocational Rehabilitation and Employment Records -VA'' (58 VA 21/22/28), a system of records that was first published at 41 FR 9294 (March 3, 1976), amended at 77 FR 42594 (July 19, 2012), and last amended and republished in its entirety at 84 FR 4138 (February 14, 2019).

Signing Authority

The Senior Agency Official for Privacy, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Faith Roy, Acting Deputy Chief Information Security Officer, Office of Information and Technology and VA Chief Privacy Officer, approved this document on July 11, 2022 for publication.

Dated: August 5, 2022

Amy L. Rose,

Program Analyst, VA Privacy Service, Office of Information Security, Office of Information and Technology, Department of Veterans Affairs.

[FR Doc. 2022–17191 Filed 8–9–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Agency Information Collection Activity Under OMB Review: Authorization To Disclose Personal Information to a Third Party—Education Benefits

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden, and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the newly proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–NEW.''

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–NEW'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 CFR 1.526(a) and 38 CFR 1.576(b).

Title: Authorization to Disclose Personal Information to a Third Party—Education Benefits, VAF 22–10278.

OMB Control Number: 2900–NEW.

Type of Review: New Information Collection (ICR).

Abstract: VA Form 22–10278 is used to release information in its custody or control in the following circumstances: where the individual identifies the particular information and consents to its use; for the purpose for which it was collected or a consistent purpose (*i.e.,* a purpose which the individual might have reasonably expected). By law, VA must have a claimants or beneficiary's written permission (an ''authorization'') to use or give out claim or benefit information for any purpose that is not contained in VA's System of Records, 58VA21/22/28 Compensation, Pension, Education and Veteran Readiness and Employment Records—VA. The claimant or beneficiary may revoke the authorization at any time, except if VA has already acted based on the claimant's permission. This form is designed to permit the beneficiary the opportunity to authorize release of information specific to their claim or benefits to a designated third party. Without this form, such information cannot be released by VA.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 87 FR 12106 on June 6, 2022, on page 34348.

Affected Public: Individuals or Households.

Estimated Annual Burden: 1,667 hours.

Estimated Average Burden Time per Respondent: 5 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 20,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–17199 Filed 8–9–22; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, et al.

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 482, 485, and 495

[CMS–1771–F]

RIN 0938–AU84

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will: revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals; make changes relating to Medicare graduate medical education (GME) for teaching hospitals; update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs). In addition it will establish new requirements and revise existing requirements for eligible hospitals and critical access hospitals (CAHs) participating in the Medicare Promoting Interoperability Program; and update policies for the Hospital Readmissions Reduction Program, Hospital Inpatient Quality Reporting (IQR) Program, Hospital VBP Program, Hospital-Acquired Condition (HAC) Reduction Program, PPS-Exempt Cancer Hospital Reporting (PCHQR) Program, and the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). It will also revise the hospital and critical access hospital (CAH) conditions of participation (CoPs) for infection prevention and control and antibiotic stewardship programs; and codify and clarify policies related to the costs incurred for qualified and non-qualified deferred compensation plans. Lastly, this final rule will provide updates on the Rural Community Hospital Demonstration Program and the Frontier Community Health Integration Project.

DATES: This final rule is effective October 1, 2022.

FOR FURTHER INFORMATION CONTACT: Donald Thompson, and Michele Hudson, (410) 786–4487 or *DAC@cms.hhs.gov*, Operating Prospective Payment, MS–DRG Relative Weights, Wage Index, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Sole Community Hospitals (SCHs), Medicare-Dependent Small Rural Hospital (MDH) Program, Low-Volume Hospital Payment Adjustment, and Critical Access Hospital (CAH) Issues.

Emily Lipkin, and Jim Mildenberger, *DAC@cms.hhs.gov*, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Adina Hersko, *Adina.Hersko@cms.hhs.gov*, New Technology Add-On Payments and New COVID–19 Treatments Add-on Payments Issues.

Mady Hue, *marilu.hue@cms.hhs.gov*, and Andrea Hazeley, *andrea.hazeley@cms.hhs.gov*, MS–DRG Classifications Issues.

Siddhartha Mazumdar, *siddhartha.mazumdar @cms.hhs,gov*, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, *jeris.smith@cms.hhs.gov*, Frontier Community Health Integration Project Demonstration Issues.

Sophia Chan, *sophia.chan@cms.hhs.gov*, Hospital Readmissions Reduction Program—Administration Issues.

Tyson Nakashima, *Tyson.Nakashima@cms.hhs.gov*, Hospital Readmissions Reduction Program—Measures Issues.

Jennifer Tate, *jennifer.tate@cms.hhs.gov*, Hospital-Acquired Condition Reduction Program—Administration Issues

Yuling Li, *yuling.li@cms.hhs.gov*, Hospital-Acquired Condition Reduction Program—Measures Issues.

Julia Venanzi, *julia.venanzi@cms.hhs.gov*, Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Administration Issues

Melissa Hager, *melissa.hager@cms.hhs.gov* and Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov*—Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, *elizabeth.goldstein@cms.hhs.gov*, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Ora Dawedeit, *ora.dawedeit@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting—Administration Issues.

Leah Domino, *leah.domino@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting Program-Measure Issues

Ariel Cress, *ariel.cress@cms.hhs.gov*, Long-Term Care Hospital Quality Reporting Program—Data Reporting Issues.

Elizabeth Holland, *elizabeth.holland@cms.hhs.gov*, Medicare Promoting Interoperability Program.

Dawn Linn, *dawn.linn@cms.hhs.gov*, Lela Strong, *lela.strong@cms.hhs.gov*, and Alpha Wilson, *alpha.wilson@cms.hhs.gov*, Conditions of Participation (CoP) Requirements for Hospitals and Critical Access Hospitals (CAHs) to Continue Reporting Data for COVID–19 and Influenza After the PHE ends as Determined by the Secretary.

SUPPLEMENTARY INFORMATION:

Tables Available Through the internet on the CMS website

The IPPS tables for this fiscal year (FY) 2023 final rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled ''FY 2023 IPPS Final rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2023 final rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1771–F. For further details on the contents of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this FY 2023 IPPS/LTCH PPS final rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact Michael Treitel, *DAC@cms.hhs.gov*.

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2023 IPPS/LTCH PPS final rule makes payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it makes payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This final rule also makes policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. In this FY 2023 final rule, we are implementing a permanent policy to cap wage index decreases as well as continuing policies to address wage index disparities impacting low wage index hospitals. We also are making changes relating to Medicare graduate medical education (GME) for teaching hospitals and new technology add-on payments.

We are establishing new requirements and revising existing requirements for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

This final rule also acknowledges feedback we received on requests for information on health impacts due to climate change, on overarching principles in measuring healthcare quality disparities in hospital quality programs and value-based purchasing programs, the LTCH QRP, and on advancing the Trusted Exchange Framework and Common Agreement (TEFCA). We thank commenters for their feedback.

Additionally, due to the impact of the COVID–19 PHE on measure data used in the Hospital VBP Program and HAC Reduction Program, we are finalizing our proposals to suppress several measures in both of those programs for purposes of FY 2023 scoring and payment adjustments. For transparency, we will continue to publicly report measure information for all measures, including suppressed measures. In addition to these measure suppressions

for the Hospital VBP Program, we are finalizing our proposal to implement a special scoring methodology for FY 2023 that results in each hospital receiving a value-based incentive payment amount that matches their 2 percent reduction to the base operating MS–DRG payment amount. Similarly, we are finalizing our proposal to suppress all six measures in the HAC Reduction Program for the FY 2023 program year. We are not finalizing our proposal to not calculate measure results or scores for the CMS PSI 90 measure. Although we will not calculate or report the CMS PSI 90 measure results for use in the HAC Reduction Program scoring calculations for the program year, we will still calculate and report CMS PSI 90 that is displayed on the main pages of the Care Compare tool hosted by HHS after confidentially reporting these results to hospitals via hospital-specific reports and a 30-day preview period. Additionally, we will continue to calculate and report measure results for the NHSN CDC HAI measures. For the FY 2023 program year, hospitals participating in the HAC Reduction Program will not be given a Total HAC score, nor will hospitals receive a payment penalty. We are also providing estimated and newly established performance standards for the Hospital VBP Program. For the Hospital Readmissions Reduction Program, we are resuming the use of the one measure (which was previously suppressed for the FY 2023 applicable period) for the FY 2024 applicable period, and incorporating measure updates to the six condition/procedure measures addressed by the Hospital Readmission Reduction Program to account for patient history of COVID–19.

Under various statutory authorities, we either discuss continued program implementation or make changes to the Medicare IPPS, the LTCH PPS, other related payment methodologies and programs for FY 2023 and subsequent fiscal years, and other policies and provisions included in this rule. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the BBRA (Public Law (Pub. L.) 106–113) and section 307(b)(1) of the BIPA (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.
- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act directs the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions.
- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.
- Section 1886(m)(5) of the Act, which requires the Secretary to reduce by two percentage points the annual update to the standard Federal rate for discharges for a long-term care hospital (LTCH) during the rate year for LTCHs that do not submit data in the form, manner, and at a time, specified by the Secretary.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub.

L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.

- Section 1899B of the Act, as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.
- Section 1861(e) of the Act provides the specific statutory authority for the hospital CoPs; section 1820(e) of the Act provides similar authority for CAHs. The hospital provision at section 1861(e)(9) of the Act authorizes the Secretary to issue regulations the Secretary deems necessary to protect the health and safety of patients receiving services in those facilities; the CAH provision at section 1820(e)(3) of the Act authorizes the Secretary to issue such other criteria as the Secretary may require.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this final rule. In general, these major provisions are being finalized as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the changes in this final rule is presented in section I.D. of the preamble of this final rule.

a. MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Pub. L. 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. The FY 2014 through FY 2017 adjustments represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.) Therefore, for FY 2023, we are making an adjustment of + 0.5 percent to the standardized amount.

b. Use of FY 2021 Data and Methodology Modifications for the FY 2023 IPPS and LTCH PPS Ratesetting

For the IPPS and LTCH PPS ratesetting, our longstanding goal is always to use the best available data overall. In section I.F. of the preamble of this final rule, we discuss our return to our historical practice of using the most recent data available for purposes of FY 2023 ratesetting, including the FY 2021 MedPAR claims and FY 2020 cost report data, with certain modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021. As discussed in greater detail in section I.F. of the preamble of this final rule, we believe that it is reasonable to assume that some Medicare beneficiaries will continue to be hospitalized with COVID–19 at IPPS hospitals and LTCHs in FY 2023. Given this expectation, we believe it is appropriate to use FY 2021 data, as the most recent available data during the period of the COVID–19 PHE, for purposes of the FY 2023 IPPS and LTCH PPS ratesetting. However, as also discussed in greater detail in section I.F. of the preamble of this final rule, we believe it is reasonable to assume based on the information available at this time that there will be fewer COVID–19 hospitalizations in FY 2023 than in FY 2021. Therefore, we are finalizing our proposal to use the FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting but with modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021.

c. Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low wage hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We also indicated our intention that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. We are finalizing our proposals for the low wage index hospital policy to continue for FY 2023, and to apply this policy in a budget neutral manner by applying an adjustment to the standardized amounts.

d. Permanent Cap on Wage Index Decreases

Consistent with section 1886(d)(3)(E) of the Act, we adjust the IPPS standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level and update the wage index annually based on a survey of wages and wage-related costs of short-term, acute care hospitals. As described in section III.N. of the preamble of this final rule, we have further considered the comments we received during the FY 2022 rulemaking recommending a permanent 5-percent cap policy to prevent large year-to-year variations in wage index values as a means to reduce overall volatility for hospitals. Under the authority at sections 1886(d)(3)(E) and 1886(d)(5)(I)(i) of the Act, for FY 2023 and subsequent years, we proposed to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, we proposed that a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We also proposed to apply the proposed wage index cap policy in a budget neutral manner through a national adjustment to the standardized amount under our authority in sections 1886(d)(3)(E) and 1886(d)(5)(I)(i) of the Act. After consideration of the public comments received, we are finalizing these proposals without modification.

e. Application of the Rural Floor

As discussed in section III.G.1. of the preamble of this final rule, based on the

district court's decision in *Citrus HMA, LLC, d/b/a Seven Rivers Regional Medical Center* v. *Becerra,* No. 1:20–cv–00707 (D.D.C.) (hereafter referred to as *Citrus*) and the comments we received, we are not finalizing our rural floor wage index policy as proposed, which would have excluded § 412.103 hospitals from the calculation of the rural floor and from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. Rather, we are finalizing a policy that calculates the rural floor as it was calculated before FY 2020. For FY 2023 and subsequent years, we are finalizing a policy to include the wage data of hospitals that have reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) and have no additional form of reclassification (MGCRB or Lugar) in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

f. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, Medicare disproportionate share hospitals (DSHs) receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this final rule, we are updating our estimates of the three factors used to determine uncompensated care payments for FY 2023. We are also continuing to use uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in conjunction with more recently available data in the calculation of Factor 2. For FY 2023, we are using the 2 most recent years of audited data on uncompensated care costs from Worksheet S–10 of the FY 2018 cost reports and the FY 2019 cost reports to calculate Factor 3 in the uncompensated care payment methodology for all eligible hospitals. In addition, for FY 2024 and subsequent fiscal years, we are using a 3-year average of the data on uncompensated care costs from Worksheet S–10 for the 3 most recent fiscal years for which audited data are available. Beginning in FY 2023, we are discontinuing the use of low-income insured days as a proxy for uncompensated care to determine Factor 3 for Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico. In addition, we are implementing certain methodological changes for calculating Factor 3 for FY 2023 and subsequent fiscal years.

We recognize that discontinuing the use of the low-income insured days proxy to calculate uncompensated care payments for Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico could result in a significant financial disruption for these hospitals. Accordingly, we are using our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to establish a new supplemental payment for IHS and Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023.

As noted in section IV.F. of this final rule, we are not moving forward with the proposed revisions to the regulations relating to the treatment of section 1115 demonstration days for purposes of the DSH adjustment in this final rule. We expect to revisit the issue of section 1115 demonstration days in future rulemaking, and we encourage interested parties to review any future proposal on this issue and to submit their comments at that time.

g. Changes to GME Payments Based on *Milton S. Hershey Medical Center, et al.* v. *Becerra* Litigation

On May 17, 2021, the U.S. District Court for the District of Columbia ruled against CMS's method of calculating direct GME payments to teaching hospitals when those hospitals' weighted full-time equivalent (FTE) counts exceed their direct GME FTE cap. In *Milton S. Hershey Medical Center, et al.* v. *Becerra,* the court ordered CMS to recalculate reimbursement owed, holding that CMS's regulation impermissibly modified the statutory weighting factors. The plaintiffs in these consolidated cases alleged that as far back as 2005, the proportional reduction that CMS applied to the weighted FTE count when the weighted FTE count exceeded the FTE cap conflicted with the Medicare statute, and it was an arbitrary and capricious exercise of agency discretion under the Administrative Procedure Act. The court held that the proportional reduction methodology impermissibly modified the weighting factors statutorily assigned to residents and fellows. The court granted the motion for summary judgment to plaintiffs' motions, denied defendant's, and remanded to the Agency so that it could recalculate plaintiffs' reimbursement payments consistent with the court's opinion.

After reviewing the statutory language regarding the direct GME FTE cap and the court's opinion, we have decided implement a modified policy to be applied prospectively for all teaching hospitals, as well as retroactively to the providers and cost years in Hershey and certain other providers as described in greater detail in section V.F.2. of the preamble of this final rule. The modified policy will address situations for applying the FTE cap when a hospital's weighted FTE count is greater than its FTE cap, but would not reduce the weighting factor of residents that are beyond their initial residency period to an amount less than 0.5. Specifically, effective for cost reporting periods beginning on or after October 1, 2001, we are specifying that if the hospital's unweighted number of FTE residents exceeds the FTE cap, and the number of weighted FTE residents also exceeds that FTE cap, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the FTE cap. If the number of weighted FTE residents does not exceed that FTE cap, then the allowable weighted FTE count for direct GME payment is the actual weighted FTE count.

h. Reduction of Hospital Payments for Excess Readmissions

We are making changes to policies for the Hospital Readmissions Reduction Program, which was established under section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating MS–DRG payment to account for excess readmissions of selected applicable conditions. For FY 2023, the reduction is based on a hospital's risk-adjusted readmission rate during a multi-year period for acute myocardial infarction (AMI), heart failure (HF), chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG)

surgery.[1] In this FY 2023 IPPS/LTCH PPS final rule, we are discussing the following policies: (1) resuming use of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) for the FY 2024 program year; (2) modification of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) to exclude patients with COVID–19 diagnosis present on admission from the measure numerator (outcome) and denominator (cohort),[2] beginning with the Hospital Specific Reports (HSRs) for the FY 2023 program year; and (3) modification of all six condition/procedure specific measures to include a covariate adjustment for patient history of COVID–19 within 12 months prior to the index admission beginning with the FY 2023 program year. In the FY 2023 IPPS/LTCH PPS proposed rule we also sought comment on updating the Hospital Readmissions Reduction Program to incorporate provider performance for socially at-risk populations.

i. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this final rule, we are finalizing our proposals to: (1) suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) and five Hospital-Acquired Infection (HAI) measures for the FY 2023 program year; and (2) update the baseline periods for certain measures for the FY 2025 program year. We are also finalizing our proposal to revise the scoring and payment methodology for the FY 2023 program year such that hospitals will not receive Total Performance Scores (TPSs). Additionally, we are finalizing our proposal to award each hospital a payment incentive multiplier that results in a value-based incentive payment that is equal to the amount withheld for the fiscal year (2 percent). We note that we are also announcing technical updates to the measures in the Clinical Outcomes Domain.

j. Hospital-Acquired Condition (HAC) Reduction Program

In this FY 2023 IPPS/LTCH PPS final rule we are finalizing several changes to the HAC Reduction Program, which was established under section 1886(p) of the Act, to provide an incentive to hospitals to reduce the incidence of hospital-acquired conditions. We refer readers to the FY 2022 IPPS/LTCH PPS final rule for further details on our measure suppression policy (86 FR 45301 through 45304). In this FY 2023 IPPS/LTCH PPS final rule, we are not finalizing our proposal to not calculate or report measure results for the CMS PSI 90 measure for the FY 2023 HAC Reduction Program. Although we will not calculate or report CMS PSI 90 measure results for use in the HAC Reduction Program scoring calculations for the program year, we will still calculate and report CMS PSI 90 that is displayed on the main pages of the Compare tool hosted by HHS after confidentially reporting these results to hospitals via CMS PSI 90 specific HSRs and a 30-day preview period. We will continue to calculate and report measure results for the NHSN CDC HAI measures.

In this FY 2023 IPPS/LTCH PPS final rule, we are finalizing our proposals to: (1) suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score, thereby not penalizing any hospital under the HAC Reduction Program FY 2023 program year; (2) suppress CY 2021 CDC NHSN HAI measures data from the FY 2024 HAC Reduction Program Year; (3) update the measure specification to the minimum volume threshold for the CMS PSI 90 measure beginning with the FY 2023 program year; (4) update the measure specifications to risk-adjust for COVID–19 diagnosis in the CMS PSI 90 measure beginning with the FY 2024 HAC Reduction Program Year; and (5) update the NHSN CDC HAI data submission requirements for newly opened hospitals beginning in the FY 2024 HAC Reduction Program.

In this FY 2023 IPPS/LTCH PPS final rule, we acknowledge feedback we received on Requests for Information from stakeholders on two topics: (1) the potential adoption of two digital National Healthcare Safety Network (NHSN) measures: the NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome measure and NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure; and (2) on overarching principles for measuring healthcare quality disparities across CMS Quality Programs. In the FY 2023 IPPS/LTCH PPS proposed rule and this final rule, we also clarified the removal of the no mapped location policy beginning with the FY 2023 program year.

k. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase.

In this FY 2023 IPPS/LTCH PPS final rule, we are finalizing several changes to the Hospital IQR Program. We are adopting 10 new measures: (1) Hospital Commitment to Health Equity beginning with the CY 2023 reporting period/FY 2025 payment determination; (2) Screening for Social Drivers of Health beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) Screen Positive Rate for Social Drivers of Health beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (4) Cesarean Birth electronic clinical quality measure (eCQM) with inclusion in the eCQM measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (5) Severe Obstetric Complications eCQM with inclusion in the eCQM measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (6) Hospital-Harm—Opioid-Related Adverse Events eCQM (NQF #3501e) inclusion in the eCQM measure set beginning with the CY 2024 reporting period/FY 2026 payment determination; (7) Global Malnutrition Composite Score eCQM (NQF #3592e) inclusion in the eCQM measure set beginning with the CY 2024 reporting period/FY 2026 payment determination; (8) Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #3559) beginning with two voluntary periods, followed by mandatory reporting for the

[1] We note that in the FY 2023 IPPS/LTCH PPS proposed rule we described the policy for FY 2017 and subsequent years, without reference to flexibility due to the COVID–19 PHE. We have updated this information to describe the policy for FY 2023.

[2] We note that in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28113) we inadvertently omitted reference to removing COVID–19 diagnosed patients from the numerator. We have corrected this omission here.

reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination; (9) Medicare Spending Per Beneficiary (MSPB) Hospital measure (NQF #2158) beginning with the FY 2024 payment determination; and (10) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA (NQF #1550) beginning with the FY 2024 payment determination. We are refining two current measures beginning with the FY 2024 payment determination: (1) Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA measure; and (2) Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) measure (NQF #2881). In this FY 2023 IPPS/LTCH PPS final rule, we acknowledge feedback we received on the potential future development and inclusion of two National Healthcare Safety Network (NHSN) measures: (1) Healthcare-Associated *Clostridioides difficile* Infection Outcome; and (2) Hospital-Onset Bacteremia & Fungemia Outcome. We thank commenters for their feedback.

We are finalizing changes to current policies related to eCQMs and hybrid measures: (1) Modification of the eCQM reporting and submission requirements to increase the number of eCQMs to be reported beginning with the CY 2024 reporting period/FY 2026 payment determination; (2) removal of the zero denominator declarations and case threshold exemption policies for hybrid measures beginning with the FY 2026 payment determination; (3) adoption of data submission and reporting requirements for patient-reported outcome-based performance measures (PRO–PMs) beginning with the FY 2026 payment determination; and (4) modification of the eCQM validation policy to increase the requirement from 75 percent to 100 percent of requested medical records, beginning with the FY 2025 payment determination.

With respect to public reporting, we are establishing a hospital designation related to maternity care to be publicly-reported on a public-facing website beginning in Fall 2023. In the FY 2023 IPPS/PPS LTCH PPS proposed rule, we sought comments on other potential associated activities regarding this designation (87 FR 28549 through 28550). Additionally, we sought comments on ongoing ways we can advance digital quality measurement and use of Fast Healthcare Interoperability Resources (FHIR) (87 FR 28486 through 28489). We thank commenters for their feedback.

l. PPS-Exempt Cancer Hospital Quality Reporting Program

Section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate.

In this FY 2023 IPPS/LTCH PPS final rule, we are finalizing our proposal to adopt a patient safety exception into the measure removal policy. We are also finalizing our proposal to begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188) (PCH–36). We are finalizing with modification our proposal to begin public display of the Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life measure (NQF #0210) (PCH–32), the Proportion of Patients Who Died from Cancer Not Admitted to Hospice measure (NQF #0215) (PCH–34), the Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life measure (NQF #0213) (PCH–33), and the Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days measure (NQF #0216) (PCH–35). In addition, along with the Hospital IQR and HAC Reduction Programs, we respond to comments received on our request for comment on the potential adoption of two digital National Healthcare Safety Network (NHSN) measures: the NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome measure and NHSN Hospital-Onset Bacteremia and Fungemia Outcome measure.

m. Medicare Promoting Interoperability Program

For CY 2023, we are finalizing several proposed changes to the Medicare Promoting Interoperability Program. Specifically, we are: (1) requiring the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure while maintaining the associated points at 10 points beginning with the EHR reporting period in CY 2023; (2) expanding the Query of PDMP measure to not only include Schedule II opioids but also Schedule III and IV drugs beginning with the CY 2023 EHR reporting period and are adding exclusions; (3) adding a new Health Information Exchange (HIE) Objective option, the Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure (requiring a yes/no response), as an optional alternative to fulfill the objective, beginning with the CY 2023 EHR reporting period; (4) modifying the Public Health and Clinical Data Exchange Objective by adding an Antibiotic Use and Antibiotic Resistance (AUR) measure in addition to the current four required measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting) beginning with the CY 2024 EHR reporting period; (5) consolidating the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective, requiring the reporting of the active engagement option selected for the measures under the objective beginning with the CY 2023 EHR reporting period, and modifying the amount of time spent at the option 1 level of active engagement (pre-production and validation) to one EHR reporting period beginning with the CY 2024 EHR reporting period; (6) modifying the scoring methodology for the Medicare Promoting Interoperability Program beginning in CY 2023; (7) instituting public reporting of certain Medicare Promoting Interoperability Program data beginning with the CY 2023 EHR reporting period; (8) removing regulation text for the objectives and measures in the Medicare Promoting Interoperability Program from paragraph (e) under 42 CFR 495.24 and adding new paragraph (f) beginning in CY 2023; and (9) adopting two new eCQMs in the Medicare Promoting Interoperability Program's eCQM measure set beginning with the CY 2023 reporting period, two new eCQMs in the Medicare Promoting Interoperability Program's eCQM measure set beginning with the CY 2024 reporting period, and modifying the eCQM data reporting and submission requirements to increase the number of eCQMs required to be reported and the total number of eCQMs to be reported beginning with the CY 2024 reporting period, which is in alignment with the eCQM updates finalized for the Hospital IQR Program.

n. Condition of Participation (CoP) Requirements for Hospitals and CAHs to Continue Reporting Data for COVID–19 and Influenza After the PHE ends as Determined by the Secretary

In this final rule, we are revising the hospital and CAH infection prevention and control CoP requirements to continue COVID–19-related reporting requirements commencing either upon the conclusion of the current COVID–19 PHE declaration or the effective date of

this proposed rule, whichever is later, and lasting until April 30, 2024 (unless the Secretary determines an earlier end date). We have withdrawn our proposal to establish additional data reporting requirements to address future PHEs related to epidemics and infectious diseases.

3. Summary of Costs and Benefits

The following table provides a summary of the costs, savings, and benefits associated with the major provisions described in section I.A.3. of the preamble of this final rule.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Adjustment for MS-DRG Documentation and Coding Changes	Section 414 of the MACRA replaced the single positive adjustment we intended to make in FY 2018 once the recoupment required by section 631 of the ATRA was complete with a 0.5 percentage point positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percentage point by section 15005 of the 21st Century Cures Act.) For FY 2023, we are making an adjustment of +0.5 percentage point to the standardized amount consistent with the MACRA.
Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care and Supplemental Payment	For FY 2023, we are updating our estimates of the three factors used to determine uncompensated care payments. We are continuing to use uninsured estimates produced by OACT as part of the development of the NHEA in conjunction with more recently available data in the calculation of Factor 2. For FY 2023, we are using the 2 most recent years of audited data on uncompensated care costs from Worksheet S–10 of the FY 2018 cost reports and the FY 2019 cost reports to calculate Factor 3 in the uncompensated care payment methodology for all eligible hospitals. In addition, for FY 2024 and subsequent fiscal years, we will calculate Factor 3 for all eligible hospitals using a 3-year average of the data on uncompensated care costs from Worksheet S-10 for the three most recent fiscal years for which audited data are available. Beginning in FY 2023, we are discontinuing the use of low-income insured days as a proxy for uncompensated care to determine Factor 3 for Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico. In addition, we are implementing certain methodological changes for calculating Factor 3 for FY 2023 and subsequent fiscal years. We project that the amount available to distribute as payments for uncompensated care for FY 2023 will decrease by approximately $318 million, as compared to our estimate of the uncompensated care payments that will be distributed in FY 2022. The uncompensated care payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges. Because we recognize that discontinuing the use of the low-income insured days proxy to calculate uncompensated care payments for IHS and Tribal hospitals and hospitals located in Puerto Rico could result in a significant financial disruption for these hospitals, we are using our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to establish a new supplemental payment for IHS and Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023. This provision is not budget neutral and we estimate the impact of the new payment will increase Medicare spending for FY 2023 by approximately $96 million.
Application of the Rural Floor	Based on the district court's decision in *Citrus HMA, LLC, d/b/a Seven Rivers Regional Medical Center v. Becerra*, and the comments we received, as discussed in section III.G.1. of the preamble of this final rule, we are not finalizing our rural floor wage index policy as proposed, which would have excluded § 412.103 hospitals from the calculation of the rural floor and from the calculation of "the wage index for rural areas in the State in which the county is located" as referred to in section 1886(d)(8)(C)(iii) of the Act. Rather, we are finalizing a policy that calculates the rural floor as it was calculated before FY 2020. For FY 2023 and subsequent years, we

Provision Description	Description of Costs, Transfers, Savings, and Benefits
	are finalizing a policy to include the wage data of hospitals that have reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) and have no additional form of reclassification (MGCRB or Lugar) in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of "the wage index for rural areas in the State in which the county is located" as referred to in section 1886(d)(8)(C)(iii) of the Act. The law requires that a national budget neutrality adjustment be applied in implementing the rural floor.
Changes to GME Payments Based on *Milton S. Hershey Medical Center, et al. v. Becerra* Litigation	After reviewing the statutory language regarding the direct GME FTE cap and the court's opinion in Milton S. Hershey Medical Center, et al. v. Becerra, we are implementing a modified policy to be applied retroactively for all teaching hospitals, Specifically, effective for cost reporting periods beginning on or after October 1, 2001, we are specifying that if the hospital's unweighted number of FTE residents exceeds the FTE cap, and the number of weighted FTE residents also exceeds that FTE cap, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the FTE cap. If the number of weighted FTE residents does not exceed that FTE cap, then the allowable weighted FTE count for direct GME payment is the actual weighted FTE count. We estimate the impact of this change for FY 2023 to be approximately $170 million.
Update to the IPPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this final rule, acute care hospitals are estimated to experience an increase of approximately $1.4 billion in FY 2023, primarily driven by: (1) a combined $2.4 billion increase in FY 2023 operating payments, including supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals, as well as changes in uncompensated care payments, and (2) a combined decrease of $ 1.0 billion resulting from estimated changes in new technology add-on payments (including the expiration of payments for technologies that were provided a one-year extension in FY 2022), the change to the GME weighting methodology, the expiration of the temporary changes to the low-volume hospital payment adjustment, and capital payment, as modeled for this final rule.
Update to the LTCH PPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this final rule, based on the best available data for the 339 LTCHs in our database, we estimate that the changes to the payment rates and factors that we present in the preamble of and Addendum to this final rule, which reflect the update to the LTCH PPS standard Federal payment rate for FY 2023, will result in an estimated increase in payments in FY 2023 of approximately $71 million.
Changes to the Hospital Readmissions Reduction Program	For the FY 2023 program year, MS-DRG reductions in payments are based on a hospital's risk-adjusted readmission rate during a multi-year period for acute myocardial infarction (AMI), heart failure (HF), chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. Overall, in this rule, we estimate that 2,273 hospitals will have their base operating MS-DRG payments reduced by their determined estimated FY 2023 hospital-specific readmission adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program would save approximately $320 million in FY 2023.
Value-Based Incentive Payments under the Hospital VBP Program	We estimate that there would be no net financial impact to the Hospital VBP Program for the FY 2023 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS-DRG payment amount reductions for that year, as estimated by the Secretary. We are finalizing our proposals which will result in hospitals not receiving a Total Performance Score (TPS) for FY 2023. The estimated amount of base operating MS-DRG payment amount reductions for the FY 2023 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2023 discharges is approximately $1.8 billion.
Changes to the HAC Reduction Program	For the FY 2023 program year, we are finalizing our proposal to suppress all six measures in the HAC Reduction Program. We are not finalizing our proposal to not calculate or report CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Although we will not use the calculated scores for the CMS PSI 90 measure

Provision Description	Description of Costs, Transfers, Savings, and Benefits
	results to implement the HAC Reduction Program for the program year we will still calculate and report CMS PSI 90 that is displayed on the main pages of the Care Compare tool hosted by HHS after confidentially reporting these results to hospitals via CMS PSI 90 specific HSRs and a 30-day preview period for the NHSN CDC HAI measures. Accordingly, for the FY 2023 HAC Reduction Program, no hospital would receive a payment reduction. As a result, for the FY 2023 program year, we anticipate reductions to the Medicare trust fund that is otherwise estimated at approximately $350 million.
Changes to the Hospital IQR Program	Across 3,150 IPPS hospitals, we estimate that our finalized changes for the Hospital IQR Program in this final rule would result in a total information collection burden increase of 746,300 hours associated with our finalized policies, and updated burden estimates and a total cost increase of approximately $23,437,906 across a 4-year period from the CY 2023 reporting period/FY 2025 payment determination through the CY 2026 reporting period/FY 2028 payment determination.
Changes to the Medicare Promoting Interoperability Program	Across 4,500 eligible hospitals and CAHs, we estimate that our finalized changes for the Medicare Promoting Interoperability Program in this final rule would result in a total information collection burden increase of 5,513 hours associated with our finalized policies, and updated burden estimates and a total cost increase of approximately $233,730 across a 2-year period from the CY 2023 EHR reporting period through the CY 2024 EHR reporting period.
Condition of Participation (CoP) Requirements for Hospitals and CAHs to Continue Reporting Data for COVID-19 and Influenza After the PHE ends as Determined by the Secretary	As detailed in section XII.B.10. of the preamble of this final rule (Collection of Information requirements), we estimate that our changes to the CoPs, which would require hospitals and CAHs to comply with continued COVID-19-related reporting provisions, will result in an estimated burden increase of 483,600 hours based on weekly reporting (52 weeks per year) of the required information by approximately 6,200 hospitals and CAHs and at an average response time of 1.5 hours for a registered nurse with an average hourly salary of $79. This would result in an estimated total of $38,204,400 for weekly reporting (or approximately $6,162 per facility).

[1]For the purpose of modeling the estimated FY 2023 payment adjustment factors that account for the suppression of the pneumonia readmission measure for this final rule, we used the data from the FY 2022 Hospital Readmissions Reduction Program for the five non-suppressed measures (that is, AMI, HF, COPD, THA/TKA, and CABG).

B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments and, beginning in FY 2023 for IHS and Tribal hospitals and hospitals located in Puerto Rico, the new supplemental payment.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2022. For discharges occurring on or after October 1, 2007, but before October 1, 2022, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). As section 50205 of the Bipartisan Budget Act extended the MDH program through FY 2022 only, for FY 2023, beginning on October 1, 2022, the MDH program will no longer be in effect absent a change in law. Because the MDH program is not authorized by statute beyond September 30, 2022, beginning October 1, 2022, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care

institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation Implemented in This Final Rule

1. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, Pub. L. 114–10) specifies a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. These adjustments follow the recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring from FYs 2014 through 2017 to fully offset $11 billion, in accordance with section 631 of the ATRA. The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.

D. Issuance of Proposed Rulemaking

In the FY 2023 IPPS/LTCH PPS proposed rule appearing in the May 10, 2022 **Federal Register** (87 FR 28108), we set forth proposed payment and policy changes to the Medicare IPPS for FY 2023 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2023.

The following is a general summary of the changes that we proposed to make.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we include the following:

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2023.
- Proposed adjustment to the standardized amounts under section 1886(d) of the Act for FY 2023 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA.
- Proposed recalibration of the MS–DRG relative weights, including a proposed 10-percent cap on decreases in an MS–DRG relative weight from one fiscal year to the next.
- A discussion of the proposed FY 2023 status of new technologies approved for add-on payments for FY 2022, a presentation of our evaluation and analysis of the FY 2023 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting) for applications not submitted under an alternative pathway, and a discussion of the proposed status of FY 2023 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.
- A proposal to use National Drug Codes (NDCs) to identify cases involving use of therapeutic agents approved for new technology add-on payments.
- A proposal to publicly post online future applications for new technology add-on payments. Specifically, beginning with the FY 2024 application cycle, we proposed to post online the completed application forms and certain related materials and updated application information submitted subsequent to the initial application submission for new technology add-on payments, with the exception of certain cost and volume information and certain additional materials (as discussed more fully in section II.F.9. of the proposed rule), no later than the issuance of the proposed rule.

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble of the proposed rule, we proposed to make revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but were not limited to, the following:

- The proposed FY 2023 wage index update using wage data from cost reporting periods beginning in FY 2019.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for FY 2023 based on the 2019 Occupational Mix Survey.
- Proposed application of the rural, imputed and frontier State floors, and continuation of the low wage index hospital policy.
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed adjustment to the wage index for acute care hospitals for FY 2023 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Proposed permanent cap on annual wage index decreases.
- Proposed labor-related share for the proposed FY 2023 wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section V. of the preamble of the proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed inpatient hospital update for FY 2023.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- Proposed payment adjustment for low-volume hospitals for FY 2023 and subsequent years.
- The statutorily required IME adjustment factor for FY 2023.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- Proposed new supplemental payment for IHS/Tribal and Puerto Rico hospitals.
- Proposed revisions to the regulations regarding the counting of days associated with section 1115 demonstrations in the Medicaid fraction.
- Discussion of statutory expiration of the MDH program at the end of FY 2022.
- Proposed requirements for payment adjustments under the Hospital Readmissions Reduction Program for FY 2023.
- The provision of estimated and newly established performance standards for the calculation of value-based incentive payments, as well as a proposal to suppress multiple measures and provide net-neutral payment adjustments under the Hospital Value-Based Purchasing Program.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2023.
- Discussion of and proposed changes relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2023.
- Proposed GME payment change in response to *Milton S. Hershey Medical Center et al* v. *Becerra* litigation.
- Proposed nursing and allied health education program Medicare Advantage (MA) add-on rates and direct GME MA percent reductions for CYs 2020 and 2021.
- Proposal to allow Medicare GME affiliation agreements within certain rural track full-time equivalent limitations.
- Proposed payment adjustment for certain clinical trial and expanded access use immunotherapy cases.

4. Proposed FY 2023 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble to the proposed rule, we discussed the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2023.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VII. of the preamble of the proposed rule, we discussed the following:

- Proposed changes to payments to certain excluded hospitals for FY 2023.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

6. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of the proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2023.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of the proposed rule, we addressed the following:

- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program.
- Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
- For the Long Term Care Hospital Quality Reporting Program (LTCH QRP), we requested information on CMS' overarching principles for measuring healthcare disparities across CMS Quality Programs, including the LTCH QRP. We also requested information on the potential adoption of one future National Healthcare Safety Network (NHSN) digital quality measure (dQM) for the LTCH QRP, as well as quality measure concepts under consideration for future years.
- Proposed changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

8. Other Proposals and Comment Solicitations Included in the Proposed Rule

Section X. of the preamble to the proposed rule includes the following:

- Proposed codification of policies related to the costs incurred for qualified and non-qualified deferred compensation plans.
- Proposed changes pertaining to the CoPs at 42 CFR part 482 for hospitals, and at 42 CFR part 485, subpart F, for CAHs.
- Solicitation of comments on the appropriateness of payment adjustments that would account for the additional resource costs for hospitals for the procurement of wholly domestically made NIOSH-approved surgical N95 respirators.

9. Other Provisions of the Proposed Rule

Section XI. of the preamble to the proposed rule includes our discussion of the MedPAC Recommendations.

Section XII. of the preamble to the proposed rule included the following:

- A descriptive listing of the public use files associated with the proposed rule.
- The collection of information requirements for entities based on our proposals.
- Information regarding our responses to public comments.

10. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2023 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We proposed to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum to the proposed rule, we addressed the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2023 for certain hospitals excluded from the IPPS.

11. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2023 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2023. We are proposed to establish the adjustments for the wage index, labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

12. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, CAHs, LTCHs and other entities.

13. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2023 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

14. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2022 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We addressed these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2022 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at *https://www.medpac.gov*.

E. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their digital health information.

To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) to facilitate collaboration with industry stakeholders to develop Health Level Seven International® (HL7) Fast Healthcare Interoperability Resources® (FHIR) standards. These standards could support the exchange and reuse of patient assessment data derived from the post-acute care (PAC) setting assessment tools, such as Minimum Data Set (MDS), Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), Long Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS), Outcome and Assessment Information Set (OASIS), and other sources.[3] [4] The PACIO Project has focused on HL7 FHIR implementation guides for functional status, cognitive status and new use cases on advance directives, re-assessment timepoints, and Speech, Language, Swallowing Cognitive communications and Hearing (SPLASCH).[5] We encourage PAC provider and health information technology (IT) vendor participation as the efforts advance. The CMS Data Element Library (DEL) continues to be updated and serves as a resource for PAC assessment data elements and their associated mappings to health IT standards, such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED).[6] The DEL furthers CMS' goal of data standardization and interoperability. Standards in the DEL can be referenced on the CMS website (*https://del.cms.gov/DELWeb/pubHome*) and in the ONC Interoperability Standards Advisory (ISA). The 2022 ISA is available at *https://www.healthit.gov/isa/sites/isa/files/inline-files/2022-ISA-Reference-Edition.pdf*.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) required HHS and ONC to take steps further interoperability for providers in settings across the care continuum.[7] Specifically, section 4003(b) of the Cures Act required ONC to take steps to advance interoperability through the development of a a Trusted Exchange Framework and Common Agreement aimed at establishing full network-to-network exchange of health information nationally. On January 18, 2022, ONC announced a significant milestone by releasing the Trusted Exchange Framework [8] and Common Agreement Version 1.[9] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement is a contract that advances those principles. The Common Agreement and the incorporated by reference Qualified Health Information Network Technical Framework Version 1 establish the technical infrastructure

[3] HL7 FHIR Release 4. Available at: *https://www.hl7.org/fhir/*.

[4] HL7 FHIR. PACIO Functional Status Implementation Guide. Available at: *https://paciowg.github.io/functional-status-ig/*.

[5] PACIO Project. Available at: *http://pacioproject.org/about/*.

[6] CMS Data Element Library Fact Sheet. Available at: *https://www.cms.gov/newsroom/fact-sheets/cms-data-element-library-fact-sheet*.

[7] Public Law 114–255, sections 4001 through 4008. Available at: *https://www.govinfo.gov/content/pkg/PLAW-114publ255/html/PLAW-114publ255.htm*.

[8] The Trusted Exchange Framework (TEF): Principles for Trusted Exchange (Jan. 2022). Available at: *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf*.

[9] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022). Available at: *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

model and governing approach for different health information networks and their users to securely share clinical information with each other, all under commonly agreed to terms. The technical and policy architecture of how exchange occurs under the Common Agreement follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at those different levels, such as health information networks, healthcare practices, hospitals, public health agencies, and Individual Access Services (IAS) Providers.[10] For more information, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement*.

We invite providers to learn more about these important developments and how they are likely to affect LTCHs.

Comment: A commenter expressed support for efforts across HHS to advance health information technology exchange and encouraged use of a standard set of data by providers and health IT vendors, including efforts through the PACIO project. The commenter also noted a recent National Academies report describing technology barriers for PAC settings due to not being eligible for previous incentives to purchase technology certified under the ONC Health IT Certification Program. The commenter supported recommendations in the report for HHS to pursue financial incentives for post-acute care settings to adopt certified health information technology in order to enable health information exchange.

Response: We will take this comment into consideration as we coordinate with Federal partners, including ONC, on interoperability initiatives, and to inform future rulemaking.

F. Use of FY 2021 Data and Methodology Modifications for the FY 2023 IPPS and LTCH PPS Ratesetting

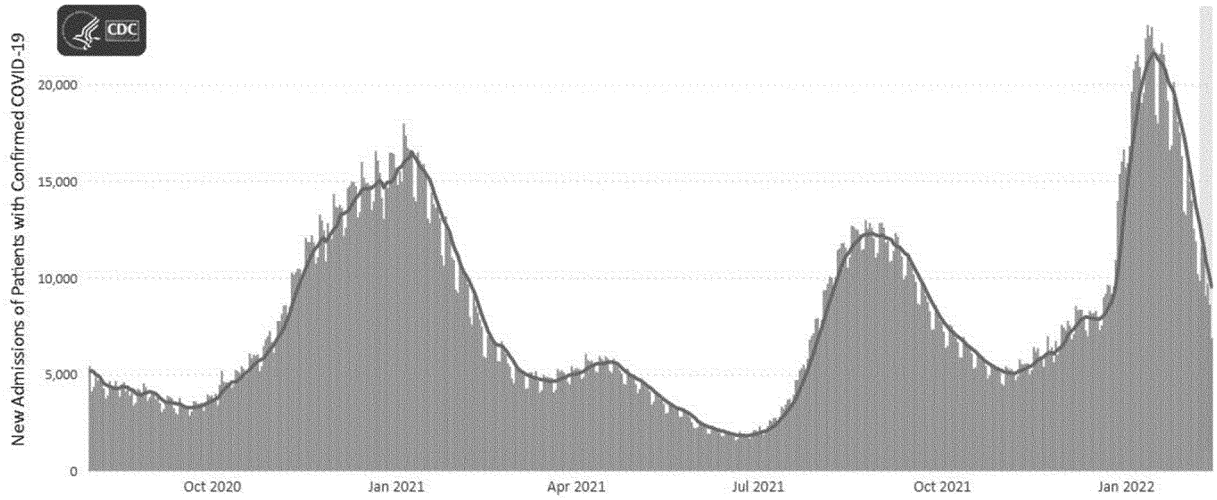
We primarily use two data sources in the IPPS and LTCH PPS ratesetting: claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year. The cost report data source is the Medicare hospital cost report data files from the most recent quarterly Healthcare Cost Report Information System (HCRIS) release. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available MedPAR data is the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking. Ordinarily, the best available cost report data is based on the cost reports beginning 3 fiscal years prior to the fiscal year that is the subject of the rulemaking. However, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44789 through 44793), as discussed in more detail below, we finalized our proposal to use FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data (the most recently available data at the time of rulemaking) was significantly impacted by the COVID–19 PHE.

As we discussed in the FY 2022 IPPS/LTCH PPS final rule, the FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset both contained data that was significantly impacted by the COVID–19 PHE, primarily in that the utilization of services at IPPS hospitals and LTCHs was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE. However, the most recent vaccination and hospitalization data from the CDC at the time of development of that rule supported our belief at the time that the risk of COVID–19 in FY 2022 would be significantly lower than the risk of COVID–19 in FY 2020 and there would be fewer COVID–19 hospitalizations for Medicare beneficiaries in FY 2022 than there were in FY 2020. Therefore, we finalized our proposal to use FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data was significantly impacted by the COVID–19 PHE, based on the belief that FY 2019 data from before the COVID–19 PHE would be a better overall approximation of the FY 2022 inpatient experience at both IPPS hospitals and LTCHs. For example, we used the FY 2019 MedPAR claims data for purposes where we ordinarily would have used the FY 2020 MedPAR claims data. We also used cost report data from the FY 2018 HCRIS file for purposes where we ordinarily would have used the FY 2019 HCRIS file (since the FY 2019 cost report data from HCRIS contained many cost reports ending in FY 2020 based on each hospital's cost reporting period).

Similar to our analysis of the FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset for the FY 2022 IPPS/LTCH PPS rulemaking, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28123 through 28125) we discussed that the FY 2021 MedPAR claims file and the FY 2020 HCRIS dataset also both contain data that was significantly impacted by the virus that causes COVID–19, primarily in that the utilization of services at IPPS hospitals and LTCHs was again generally markedly different for certain types of services in FY 2021 than would have been expected in the absence of the virus that causes COVID–19. Specifically, the share of admissions at IPPS hospitals and LTCHs for MS–DRGs and MS–LTC–DRGs associated with the treatment of COVID–19 continued to remain significantly higher than levels prior to the COVID–19 PHE. For example, in FY 2019, the share of IPPS cases and LTCH PPS standard Federal payment rate cases grouped to MS–DRG and MS–LTC–DRG 177 (Respiratory infections and inflammations with MCC) was approximately 1 percent and 2 percent, respectively. In comparison, in FY 2021, the share of IPPS cases and LTCH PPS standard Federal payment rate cases grouped to MS–DRG 177 was approximately 6 percent and 8 percent, respectively.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28123 through 28124), we reviewed the most recent data from the CDC on new inpatient hospital admissions of patients with confirmed COVID–19. We presented this CDC graph which illustrates new inpatient hospital admissions of patients with confirmed COVID–19 from August 1, 2020 through February 15, 2022 (*https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/02182022/images/hospitalizations_02182022.jpg?_=35767*, accessed February 22, 2022).

[10] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.



We stated that the low point of the graph (late June 2021) approximately coincides with the time of the development of the FY 2022 IPPS/LTCH PPS final rule and generally supports, in conjunction with the other factors discussed in that rulemaking (including the most recent vaccination data from the CDC), our assumption in the final rule that the FY 2022 time period would be more similar to the time period prior to the PHE. We stated that the graph also shows that the virus that causes COVID–19 has continued to significantly impact hospitalizations for the time period subsequent to the development of the FY 2022 IPPS/LTCH PPS final rule.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28124), we also presented information from the CDC on the likelihood of future COVID–19 variants. We noted that the most recent increase in hospitalizations was primarily associated with the Omicron variant of the virus [11] and that the CDC has stated that new variants will continue to emerge. Viruses constantly change through mutation and sometimes these mutations result in a new variant of the virus. The CDC and other public health organizations monitor all variants of the virus that causes COVID–19 in the United States and globally. Scientists monitor all variants but may classify certain ones as variants being monitored, variants of interest, variants of concern and variants of high consequence. Some variants spread more easily and quickly than other variants, which may lead to more cases of COVID–19. Even if a variant causes less severe disease in general, an increase in the overall number of cases could cause an increase in hospitalizations (see *https://www.cdc.gov/coronavirus/2019-ncov/variants/about-variants.html*, accessed February 25, 2022).

Given the effects of the virus that causes COVID–19 in the Medicare FY 2020 data, the Medicare FY 2021 data, and the CDC hospitalization data, coupled with the expectation for future variants, in the proposed rule we stated our belief that it is reasonable to assume that some Medicare beneficiaries will continue to be hospitalized with COVID–19 at IPPS hospitals and LTCHs in FY 2023. Accordingly, we stated that we believe it would be appropriate to use FY 2021 data, specifically the FY 2021 MedPAR claims file and the FY 2020 HCRIS dataset (which contains data from many cost reports ending in FY 2021 based on each hospital's cost reporting period) as the most recent available data during the period of the COVID–19 PHE, for purposes of the FY 2023 IPPS and LTCH PPS ratesetting. However, we also stated our belief that it would be reasonable to assume based on the information available at the time that there will be fewer COVID–19 hospitalizations in FY 2023 than in FY 2021 given the more recent trends in the CDC hospitalization data since the Omicron variant peak in January, 2022. Accordingly, because we anticipated Medicare inpatient hospitalizations for COVID–19 would continue in FY 2023 but at a lower level, we proposed to use FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting but with modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021.

First, we proposed to modify the calculation of the FY 2023 MS–DRG and MS–LTC–DRG relative weights. We observed that COVID–19 cases were impacting the relative weights as calculated using the FY 2021 MedPAR data for a few COVID–19-related MS–DRGs and MS–LTC–DRGs. As an example, for MS–DRG and MS–LTC–DRG 870 (Septicemia or Severe Sepsis with MV >96 hours), the MS–DRG and MS–LTC–DRG relative weights calculated using the FY 2021 MedPAR data are approximately 9 and 3 percent higher, respectively, compared to their relative weights if calculated excluding COVID–19 cases. Because this MS–DRG contains a mix of COVID–19 cases and non-COVID–19 cases with different average costs, the relative weight for this MS–DRG is dependent on that mix of cases. As stated in the proposed rule, we believed it is reasonable to assume that there would be fewer COVID–19 hospitalizations among Medicare beneficiaries in FY 2023 than there were in FY 2021; however, we also stated that it is not possible to know precisely how COVID–19 hospitalizations in FY 2023 will compare to FY 2021. We stated our belief that averaging the relative weights as calculated with and without the COVID–19 cases reflected in the FY 2021 MedPAR data would reflect a reasonable estimation of the case mix for FY 2023 based on the information available at the time, and more accurately estimate the relative resource use for the cases treated in FY 2023. Therefore, we proposed to calculate the relative weights for FY 2023 by first calculating two sets of weights, one including and one excluding COVID–19 claims, and then averaging the two sets of relative weights to determine the proposed FY 2023 relative weight values. We believed this proposed modification to our relative weight setting methodology would appropriately reduce, but not remove entirely, the effect of COVID–19 cases

[11] *https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html.*

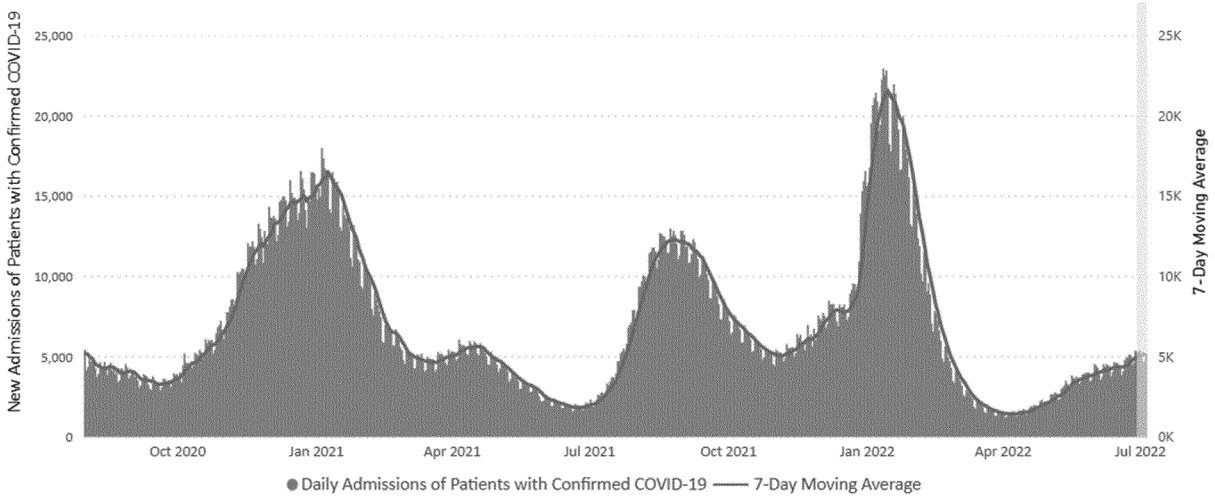
on the relative weight calculations, consistent with our expectation that Medicare inpatient hospitalizations for COVID–19 will continue in FY 2023 at a lower level as compared to FY 2021, and provide a more accurate estimate of relative resource use for FY 2023 than if we were to calculate the proposed relative weights using all applicable cases in the FY 2021 data.

We also proposed to modify our methodologies for determining the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases. The methodologies for determining both of these outlier fixed-loss amounts include calculating and applying a charge inflation factor to increase charges from the claim year to the rulemaking year, as well as calculating and applying cost-to-charge ratio (CCR) adjustment factors to adjust CCRs used to make payments in the current year to the rulemaking year. The charge inflation factors calculated using the 2 most recently available years of MedPAR claims data (FY 2020 and FY 2021) that would ordinarily be used for the FY 2023 proposed rule to inflate the charges on the FY 2021 MedPAR claims were abnormally high as compared to recent historical levels prior to the PHE (for example, for the IPPS, approximately 10 percent based on the FY 2020 and FY 2021 MedPAR claims data as compared to approximately 6 percent based on the FY 2018 and FY 2019 MedPAR claims data). Furthermore, the IPPS operating and capital CCR adjustment factors calculated based on the percentage changes in the CCRs from the December 2020 update of the Provider Specific File (PSF) to the December 2021 update of the PSF that would ordinarily be used for the FY 2023 proposed rule to adjust the CCRs from the December 2021 update of the PSF were also abnormally high as compared to recent historical levels prior to the PHE (for example, for the IPPS operating CCR adjustment factor, a factor of approximately 1.03 based on the December 2020 and December 2021 updates to the PSF as compared to a factor of approximately 0.97 based on the March 2019 and March 2020 updates to the PSF). In the proposed rule, we stated our belief that these abnormally high charge inflation and CCR adjustment factors as compared to historical levels were partially due to the high number of COVID–19 cases with higher charges that were treated in IPPS hospitals and LTCHs in FY 2021. We also stated our belief that there will be fewer COVID–19 cases in FY 2023 than in FY 2021 and that therefore, we do not believe it is reasonable to assume charges and CCRs will continue to increase at these abnormally high rates. Consequently, when determining the FY 2023 outlier fixed-loss amounts for IPPS cases and LTCH PPS standard Federal payment rate cases, we proposed to inflate the charges on the FY 2021 MedPAR claims using charge inflation factors computed by comparing the average covered charge per case in the March 2019 MedPAR file of FY 2018 to the average covered charge per case in the March 2020 MedPAR file of FY 2019, which is the last 1-year period prior to the COVID–19 PHE. We also proposed to adjust the CCRs from the December 2021 update of the PSF by comparing the percentage change in the national average case-weighted CCR from the March 2019 update of the PSF to the national average case-weighted CCR from the March 2020 update of the PSF, which is the last 1-year period prior to the COVID–19 PHE. We stated our belief that using the charge inflation factors and CCR adjustment factors derived from data prior to the COVID–19 PHE would provide a more reasonable approximation of the increase in costs that will occur from FY 2021 to FY 2023 because we do not believe the charge inflation that has occurred during the PHE will continue as the number of higher cost COVID–19 cases declines.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28740 through 28741) we also requested comments on, as an alternative to our proposed approach, the use of the FY 2021 data for purposes of FY 2023 ratesetting without these proposed modifications to our usual methodologies for the calculation of the FY 2023 MS–DRG and MS–LTC–DRG relative weights or the usual methodologies used to determine the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases. We noted that the FY 2023 outlier fixed-loss amount would be significantly higher under this alternative approach. In order to illustrate the effect of our proposed modifications on the relative weights and fixed loss amount, we made available supplemental information, including the relative weights and fixed-loss amount calculated without the proposed modifications to our usual methodologies.

The comments we received on our proposal to use FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting were focused on the specific use of FY 2021 data when determining the FY 2023 relative weights or outlier fixed-loss amounts. Therefore, we refer the reader to section II.E. of the preamble of this final rule for our summary and response to comments received on our proposed use of FY 2021 data and our proposed modifications to our usual methodology when determining the FY 2023 IPPS MS–DRG relative weights. We refer the reader to section VIII.B. of the preamble of this final rule for our summary and response to comments received on our proposed use of FY 2021 data and our proposed modifications to our usual methodology when determining the FY 2023 LTCH PPS MS–LTC–DRG relative weights. We refer the reader to section II.A.4. of the addendum to this final rule for our summary and response to comments received on our proposed use of FY 2021 data and our proposed modifications to our usual methodology when determining the FY 2023 outlier fixed-loss amounts for IPPS cases. We refer the reader to section V.D.3. of the Addendum to this final rule for our summary and response to comments received on our proposed use of FY 2021 data and our proposed modifications to our usual methodology when determining the FY 2023 outlier fixed-loss amounts for LTCH PPS standard Federal payment rate cases.

Since the publication of the proposed rule, we have continued to monitor hospitalization data reported by the CDC. This CDC graph illustrates new inpatient hospital admissions of patients with confirmed COVID–19 from August 1, 2020 through July 6, 2022 (*https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/07082022/images/Hospitalizations.png?_=90548*, accessed July 08, 2022).



The graph shows that new COVID–19 hospital admissions reached a low point in early April 2022, however have steadily increased since.

After reviewing the latest CDC hospitalization data, coupled with the expectation for future variants,[12] we continue to believe that it is reasonable to assume that some Medicare beneficiaries will continue to be hospitalized with COVID–19 at IPPS hospitals and LTCHs in FY 2023. We also continue to believe that it would be reasonable to assume based on the information available at this time that there will be fewer COVID–19 hospitalizations in FY 2023 than in FY 2021 given that the current levels of hospitalizations are much lower than the Omicron variant peak in January 2022.

Therefore, after considering the comments received and based on our evaluation of the information available at this time, we are finalizing our proposal to use FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting. (That is, the FY 2021 MedPAR claims file and the FY 2020 HCRIS dataset (which contains data from many cost reports ending in FY 2021 based on each hospital's cost reporting period).) We are also finalizing, as proposed, modifications to our usual methodology for determining the FY 2023 IPPS MS–DRG relative weights and FY 2023 LTCH PPS MS–LTC–DRG relative weights. Specifically, for FY 2023, we calculated the relative weights by first calculating two sets of weights, one including and one excluding COVID–19 claims, and then averaging the two sets of relative weights to determine the final relative weight values. The finalization of our proposal to use FY 2021 data and to modify our methodology for determining the FY 2023 IPPS MS–DRG relative weights is discussed in greater detail in section II.E. of the preamble of this final rule. The finalization of our proposal to use FY 2021 data and to modify our methodology for determining the FY 2023 LTCH PPS MS–LTC–DRG relative weights is discussed in greater detail in section VIII.B. of the preamble of this final rule.

As discussed in section II.A.4. and section V.D.3. of the addendum to this final rule, we received many comments supportive of our proposed modifications to our usual methodologies for determining the FY 2023 IPPS and LTCH PPS outlier fixed-loss amounts. As discussed in these sections, after considering comments received, we are finalizing our proposal to inflate the charges on the FY 2021 MedPAR claims using charge inflation factors computed by comparing the average covered charge per case in the March 2019 MedPAR file of FY 2018 to the average covered charge per case in the March 2020 MedPAR file of FY 2019, which is the last 1-year period prior to the COVID–19 PHE. We are also finalizing our proposal to adjust the CCRs from the March 2021 update of the PSF by comparing the percentage change in the national average case-weighted CCR from the March 2019 update of the PSF to the national average case-weighted CCR from the March 2020 update of the PSF, which is the last 1-year period prior to the COVID–19 PHE.

We also received many comments that suggested other modifications CMS should make to our usual methodologies for determining the FY 2023 IPPS and LTCH PPS outlier fixed-loss amounts. As also discussed in section II.A.4. and section V.D.3. of the addendum to this final rule, after consideration of the comments received, we are modifying our proposed methodologies for establishing the FY 2023 IPPS and LTCH PPS outlier fixed-loss amounts by calculating the FY 2023 IPPS and LTCH PPS outlier fixed-loss amounts as averages of the fixed-loss amounts as calculated including and excluding COVID–19 claims. We believe this adjustment to our proposed methodology will better reflect a reasonable estimation of the case mix for FY 2023 based on the information available at this time and is also consistent with the approach we are finalizing for determining the FY 2023 IPPS MS–DRG and LTCH PPS MS–LTC–DRG relative weights.

In addition, as discussed in section II.A.4. of the Addendum to this final rule, after consideration of comments received, we are also further modifying our proposed methodology for establishing the FY 2023 IPPS outlier fixed-loss amount by including the increases in payments for COVID–19 cases provided by the CARES Act in the calculation of the outlier fixed-loss amount.

II. Changes to Medicare Severity Diagnosis–Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment

[12] *https://www.cdc.gov/coronavirus/2019-ncov/variants/about-variants.html.*

for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. Adoption of the MS–DRGs and MS–DRG Reclassifications

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2022 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085, 83 FR 41158 through 41258, 84 FR 42058 through 42165, 85 FR 58445 through 58596, 86 FR 44795 through 44961, respectively).

C. FY 2023 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Pub. L. 110–90 and the Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA).

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percentage points to the national standardized amount. We provided for phasing in this −4.8 percentage point adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percentage points for FY 2008, −1.8 percentage points for FY 2009, and −1.8 percentage points for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percentage point for FY 2008 and −0.9 percentage point for FY 2009.

As discussed in prior year rulemakings, and most recently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56780 through 56782), we implemented a series of adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90, based on a retrospective review of FY 2008 and FY 2009 claims data. We completed these adjustments in FY 2013 but indicated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53275) that delaying full implementation of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated, and that these overpayments could not be recovered under Public Law 110–90.

In addition, as discussed in prior rulemakings and most recently in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38008 through 38009), section 631 of the American Taxpayer Relief Act of 2012 (ATRA) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

2. Adjustments Made for FYs 2018, 2019, 2020, 2021, and 2022 as Required Under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. In the FY 2017 rulemaking, we indicated that we would address the adjustments for FY 2018 and later fiscal years in future rulemaking. Section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted on December 13, 2016, amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the adjustment for FY 2018 from a 0.5 percentage point positive adjustment to a 0.4588 percentage point positive adjustment. As we discussed in the FY 2018 rulemaking, we believe the directive under section 15005 of Public Law 114–255 is clear. Therefore, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38009) for FY 2018, we implemented the required +0.4588 percentage point adjustment to the standardized amount. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41157), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42057), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58444 and 58445), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 44794 and 44795), consistent with the requirements of section 414 of the MACRA, we implemented 0.5 percentage point positive adjustments to the standardized amount for FY 2019, FY 2020, FY 2021, and FY 2022, respectively. We indicated the FY 2018, FY 2019, FY 2020, FY 2021, and FY 2022 adjustments were permanent adjustments to payment rates. We also

stated that we plan to propose a future adjustment required under section 414 of the MACRA for FY 2023 in future rulemaking.

3. Adjustment for FY 2023

Consistent with the requirements of section 414 of the MACRA, we proposed to implement a 0.5 percentage point positive adjustment to the standardized amount for FY 2023. We stated that this would constitute a permanent adjustment to payment rates. We also stated that this proposed 0.5 percentage point positive adjustment is the final adjustment prescribed by section 414 of the MACRA. Along with the 0.4588 percentage point positive adjustment for FY 2018, and the 0.5 percentage point positive adjustments for FY 2019, FY 2020, FY 2021, and FY 2022, this final adjustment will result in combined positive adjustment of 2.9588 percentage points (or the sum of the adjustments for FYs 2018 through 2023) to the standardized amount.

We received no public comments on the proposed adjustment for FY 2023 and are finalizing our proposal to implement a 0.5 percentage point positive adjustment to the standardized amount for FY 2023. As indicated, this finalized 0.5 percentage point positive adjustment for FY 2023 is the final adjustment prescribed by section 414 of the MACRA.

D. Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for FY 2023 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for FY 2023 MS–DRG Updates

Given the need for more time to carefully evaluate requests and propose updates, as discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38010), we changed the deadline to request updates to the MS–DRGs to November 1 of each year, which provided an additional five weeks for the data analysis and review process. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32472), we stated that with the continued increase in the number and complexity of the requested changes to the MS–DRG classifications since the adoption of ICD–10 MS–DRGs, and to consider as many requests as possible, more time is needed to carefully evaluate the requested changes, analyze claims data, and consider any proposed updates. We further stated we were changing the deadline to request changes to the MS–DRGs to October 20 of each year to allow for additional time for the review and consideration of any proposed updates. However, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58445), due to the unique circumstances for the FY 2021 IPPS/LTCH PPS final rule for which we waived the delayed effective date, we maintained the deadline of November 1, 2020 for FY 2022 MS–DRG classification change requests. We also noted that we expected to reconsider a change in the deadline beginning with comments and suggestions submitted for FY 2023. In the FY 2022 IPPS/LTCH PPS proposed rule, we stated that while we continue to believe that a change in the deadline from November 1 to October 20 would provide hospitals sufficient time to assess potential impacts and inform future MS–DRG recommendations, we were maintaining the deadline of November 1 for FY 2023 MS–DRG classification change requests. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44795), we received public comments expressing support for a future change to the deadline for requesting updates to the MS–DRG classifications from November 1 to October 20, and we noted in response that we may consider any changes to the deadline or frequency for submissions of requests for MS–DRG classification changes for future fiscal years. Beginning with FY 2024 MS–DRG classification change requests, we are changing the deadline to request changes to the MS–DRGs to October 20 of each year to allow for additional time for the review and consideration of any proposed updates. As previously discussed, we continue to believe such a change would allow hospitals sufficient time to assess potential impacts and inform future MS–DRG recommendations, while also providing CMS the additional time needed for evaluation of the requested changes, analysis of claims data, and consideration of any proposed updates.

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, we are also changing the process for submitting requested updates to the MS–DRG classifications, beginning with the FY 2024 MS–DRG classification change requests. CMS is in the process of implementing a new electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), for users to submit new technology add-on payment applications, requests for ICD–10–PCS procedure codes, and other requests. To simplify and streamline the process for submission of standardized applications and requests that inform payment policy under the IPPS, we will also be using this new system for submission of MS–DRG classification change requests. We believe that submission of MS–DRG reclassification requests through MEARIS™ will not only help CMS to track such requests, but it will also create efficiencies for requestors when compared to the previous submission process.

Accordingly, beginning with the FY 2024 MS–DRG classification change requests, CMS will only accept such requests submitted via MEARIS,™ and will no longer consider any such requests that are sent via email. We note that, beginning April 5, 2022, MEARIS™ became available for users to begin gaining familiarity with this new approach for submitting MS–DRG classification change requests. MEARIS,™ including the mechanism for submitting MS–DRG classification change requests, can be accessed at: *https://mearis.cms.gov*. As stated in the proposed rule, within MEARIS™ we have built in several resources to support users, including a ''Resources'' section (available at *https://mearis.cms.gov/public/resources*) and technical support available under ''Useful Links'' at the bottom of the MEARIS™ site. Questions regarding the MEARIS™ system can be submitted to CMS using the form available under ''Contact'' at: *https://mearis.cms.gov/public/resources?app=msdrg*.

We also note that, as discussed in section II.D.17. of the preamble of the proposed rule and this final rule, effective January 5, 2022, MEARIS™ was made available for users to begin gaining familiarity with a new approach

and process to submit ICD–10–PCS procedure code requests.

As noted previously, interested parties had to submit MS–DRG classification change requests for FY 2023 by November 1, 2021. As we have discussed in prior rulemaking, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change. We note in the discussion that follows those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking. Interested parties should submit any comments and suggestions for FY 2024 by October 20, 2022 via the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home*.

We provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 40, in connection with the FY 2023 IPPS/LTCH PPS proposed rule so that the public can better analyze and understand the impact of the proposals included in the proposed rule. We noted that this test software reflected the proposed GROUPER logic for FY 2023. Therefore, it included the new diagnosis and procedure codes that are effective for FY 2023 as reflected in Table 6A.—New Diagnosis Codes—FY 2023 and Table 6B.—New Procedure Codes—FY 2023 that were associated with the proposed rule and did not include the diagnosis codes that are invalid beginning in FY 2023 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2023 associated with the proposed rule. We noted that at the time of the development of the proposed rule there were no procedure codes designated as invalid for FY 2023, and therefore, there was no Table 6D—Invalid Procedure Codes—FY 2023 associated with the proposed rule. Those tables were not published in the Addendum to the proposed rule, but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to the proposed rule. Because the diagnosis codes no longer valid for FY 2023 are not reflected in the test software, we made available a supplemental file in Table 6P.1a that includes the mapped Version 40 FY 2023 ICD–10–CM codes and the deleted Version 39.1 FY 2022 ICD–10–CM codes that should be used for testing purposes with users' available claims data. Therefore, users had access to the test software allowing them to build case examples that reflect the proposals that were included in the proposed rule. In addition, users were able to view the draft version of the ICD–10 MS–DRG Definitions Manual, Version 40.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 40, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 40, and the supplemental mapping files in Table 6P.1a of the FY 2022 and FY 2023 ICD–10–CM diagnosis codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

Following are the changes that we proposed to the MS–DRGs for FY 2023. We invited public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in the proposed rule. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. In other cases, we proposed to maintain the existing MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. As discussed in section I.F of the preamble of the proposed rule, we proposed to use the FY 2021 MedPAR data for purposes of this FY 2023 IPPS rulemaking, with certain proposed modifications to the relative weight and outlier methodologies. For the FY 2023 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2021 update of the FY 2021 MedPAR file, which contains hospital bills received from October 1, 2020 through September 30, 2021, for discharges occurring through September 30, 2021. In our discussion of the proposed MS–DRG reclassification changes, we referred to these claims data as the ''September 2021 update of the FY 2021 MedPAR file.''

In this FY 2023 IPPS/LTCH PPS final rule, we summarize the public comments we received on our proposals, present our responses, and state our final policies. For this FY 2023 final rule, we generally did not perform any further MS–DRG analysis of claims data. Therefore, the MS–DRG analysis is based on ICD–10 claims data from the September 2021 update of the FY 2021 MedPAR file, as set forth in the proposed rule, except as otherwise noted.

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. We stated our belief that applying these criteria to the NonCC subgroup would better reflect resource stratification as well as promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs. We noted that in our analysis of MS–DRG classification requests for FY 2021 that were received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups. We also noted that the application of the NonCC subgroup criteria going forward may result in modifications to certain MS–DRGs that are currently split into three severity levels and result in MS–DRGs that are split into two severity levels. We stated that any proposed modifications to the MS–DRGs would be addressed in future rulemaking consistent with our annual process and reflected in Table 5—Proposed List of Medicare Severity Diagnosis Related Groups (MS–DRGs),

Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay for the applicable fiscal year.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798), we finalized a delay in applying this technical criterion to existing MS–DRGs until FY 2023 or future rulemaking, in light of the PHE. Commenters recommended that a complete analysis of the MS–DRG changes to be proposed for future rulemaking in connection with the expanded three-way severity split criteria be conducted and made available to enable the public an opportunity to review and consider the redistribution of cases, the impact to the relative weights, payment rates, and hospital case mix to allow meaningful comment prior to implementation.

In our analysis of the MS–DRG classification requests for FY 2023 that we received by November 1, 2021, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the following table.

Criteria Number	**Three-Way Split** 123 (MCC vs CC vs NonCC)	**Two-Way Split** 1_23 MCC vs (CC+NonCC)	**Two-Way Split** 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three way split within the base MS-DRG	R2 > 3.0 for the two way 1_23 split within the base MS-DRG	R2 > 3.0 for the two way 12_3 split within the base MS-DRG

In general, once the decision has been made to propose to make further modifications to the MS–DRGs as described previously, such as creating a new base MS–DRG, or in our evaluation of a specific MS–DRG classification request to split (or subdivide) an existing base MS–DRG into severity levels, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS–DRG, we typically evaluate the most recent year of MedPAR claims data available. For example, in the FY 2023 IPPS/LTCH PPS proposed rule we stated our MS–DRG analysis was based on ICD–10 claims data from the September 2021 update of the FY 2021 MedPAR file. However, in our evaluation of requests to split an existing base MS–DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we typically analyze the most recent 2 years of data. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS–DRG is warranted is to determine if all the criteria are satisfied for a three-way split. If the criteria fail, the next step is to determine if the criteria are satisfied for a two-way split. If the criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS–DRG. If the three-way split fails on any one of the five criteria and all five criteria for both two-way splits (1_23 and 12_3) are met, we would apply the two-way split with the highest R2 value. We note that if the request to split (or subdivide) an existing base MS–DRG into severity levels specifies the request is for either one of the two-way splits (1_23 or 12_3), in response to the specific request, we will evaluate the criteria for both of the two-way splits,

however we do not also evaluate the criteria for a three-way split.

In the FY 2023 IPPS/LTCH PPS proposed rule, we stated that using the September 2021 update of the FY 2021 MedPAR file, we analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2023. We noted that findings from our analysis indicated that approximately 41 MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. Specifically, we found that applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would result in the deletion of 123 MS–DRGs (41 MS–DRGs × 3 severity levels = 123) and the creation of 75 new MS–DRGs. We further noted that these updates would also involve a redistribution of cases, which would impact the relative weights, and, thus, the payment rates proposed for particular types of cases. We referred the reader to Table 6P.1b associated with the proposed rule for the list of the 123 MS–DRGs that would be subject to deletion and the list of the 75 new MS–DRGs that would be proposed for creation for FY 2023 under this policy if the NonCC subgroup criteria were applied.

We stated in the proposed rule that in light of the ongoing public health emergency (PHE), we continue to have concerns about the impact of implementing this volume of MS–DRG changes at this time, and believe it may be appropriate to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs to maintain more stability in the current MS–DRG structure and until such time additional analyses can be performed to assess impacts, as discussed in response to comments in the FY 2022 IPPS/LTCH PPS final rule. Therefore, we proposed to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2023, and to instead maintain the current structure of the 41 MS–DRGs that currently have a three-way severity level split (total of 123 MS–DRGs) that would otherwise be subject to these criteria. We stated that we intend to address the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split in future rulemaking.

Comment: Commenters expressed overwhelming support for our proposal to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2023 and to maintain the current structure of the MS–DRGs. A few commenters who agreed with the proposal to delay the application of the NonCC subgroup criteria also requested that CMS provide interested parties with an opportunity to review and comment on impacts to the relative weights before a proposal is finalized. The commenters stated it would be helpful if CMS made claims data available, including volumes by MS–DRG, that support the proposal to reduce the 123 MS–DRGs.

Response: We thank the commenters for their support. In response to the commenters who requested the opportunity to review and comment on impacts to the relative weights before a proposal is finalized, we intend to provide a comprehensive analysis in future rulemaking based on the comments and feedback we have received. We are providing the claims data from the September 2021 update of the FY 2021 MedPAR file that was reviewed for FY 2023 in our analyses of how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would have potentially affected the MS–DRG structure beginning in FY 2023. We refer the reader to Table 6P.1b associated with this final rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

Comment: A commenter who strongly agreed with the proposal to delay the application of the NonCC subgroup criteria stated that in addition to providing a detailed explanation and impact files in the future, that CMS should consider clarifying and addressing the following issues: why the list of MS–DRGs that were proposed to be removed in FY 2022 is not the same list of MS–DRGs proposed to be removed for FY 2023, why the list of MS–DRGs that were proposed to become a single, base MS–DRG for FY 2022 now appear to meet the criteria for a three-way severity level split for FY 2023, and why MS–DRGs proposed to maintain a three-way severity level split for FY 2022 now appear to meet the criteria for a two-way or three-way severity level split for FY 2023. This commenter also stated that the MS–DRGs displayed in Table 6P.1b associated with the proposed rule include a list of MS–DRGs that would be subject to deletion and a list of MS–DRGs that would be proposed for creation with XXX for the numbers. According to the commenter, many of the listed MS–DRGs have the same narrative description, however, it appears they would obtain a new MS–DRG number. The commenter questioned why MS–DRGs with the same description would have new MS–DRG numbers assigned. This commenter also suggested that CMS consider patient case-mix with regard to volumes, and stated Medicare would not have the volume for the obstetric related MS–DRGs. The commenter requested that CMS also examine the impact of maternal health quality initiatives and maternity hospital designation in connection with the solicitation for comments on low volume MS–DRGs. Lastly, the commenter recommended that CMS utilize two years of good data to examine the impact of the proposed redistribution in future analyses and determine if the proposed MS–DRG changes and associated relative weights appropriately reflect resource consumption.

Response: We appreciate the commenter's feedback. We acknowledge that the list of MS–DRGs identified as potentially subject to removal for FY 2022 differs from the list of MS–DRGs identified as potentially subject to removal and provided for FY 2023 in connection with the NonCC subgroup criteria discussion. We also acknowledge that the list of MS–DRGs identified as potentially subject to creation for FY 2022 differs from the list of MS–DRGs identified as potentially subject to removal and provided for FY 2023 in connection with the NonCC subgroup criteria discussion. The lists differ as a result of the claims data that was analyzed for our MS–DRG analysis and rulemaking each fiscal year. We provided the results of both the FY 2019 and FY 2020 MedPAR claims data as displayed in Table 6P.11 in association with the FY 2022 IPPS/LTCH PPS final rule (available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*).

By comparison, for FY 2023, consistent with our finalized policy to use the FY 2021 MedPAR data for purposes of this FY 2023 rulemaking, we have provided the FY 2021 MedPAR claims data for the listed MS–DRGs in Table 6P.1b in association with this final rule, as noted earlier in this section. Because there is variation in the claims data reported from year to year, it is expected that there may be fluctuations in the data that could affect the list of MS–DRGs potentially subject to change in connection with the application of the NonCC subgroup criteria for a particular fiscal year. However, we believe that reliability and stability of the data is an important consideration with respect to the

application of the NonCC subgroup criteria and will give careful consideration to the number of years of data to analyze in connection with any future proposed policy changes as well as the impacts on relative weights, as we continue to assess all the comments and feedback we have received, particularly in light of the ongoing public health emergency. We also take this opportunity to note that the listed MS–DRGs as displayed in the tables (for both FY 2022 and FY 2023) are for illustrative purposes as the intent was to show the MS–DRGs that would potentially be subject to deletion and the MS–DRGs that would potentially be subject to creation if the NonCC subgroup criteria were to be applied for the applicable fiscal year. Because we did not propose the application of these criteria to existing MS–DRGs with a three-way severity level split for either FY 2022 or FY 2023, and we have not yet completed the comprehensive impact analysis of any such future proposed changes, as previously discussed, we are clarifying that both the MS–DRG numbers and MS–DRG titles that may eventually be subject to change in connection with a future proposal to apply the NonCC subgroup criteria may, in the interim, be subject to further modifications as a result of our annual review of the MS–DRG classifications. As such, any future proposed MS–DRG changes will be considered in connection with the analysis that is performed for application of the MCC, CC and NonCC subgroup criteria to the MS–DRGs that are in effect at that time.

In response to the commenter's question regarding why new MS–DRG numbers would be considered, we note that new MS–DRG numbers are preferred because we anticipate that individuals, payers, and organizations conducting analysis would need to be aware if proposed changes to base DRG concepts are made to allow them time to adjust their programs, analyses, or queries that may have hard coded the DRG numbers. Other agencies that utilize MS–DRGs may perform minimal updates to their relative weights, quality risk adjustment or exclusion criteria and only focus on new MS–DRGs, thereby potentially creating additional operational or system challenges if an existing MS–DRG number were to be reused. To minimize confusion for those who rely on MS–DRG concepts year to year, and avoid unintended consequences from the reuse of an existing DRG number for a different concept, we believe it is appropriate to consider revisions to both the MS–DRG number and corresponding description.

Comment: Other commenters requested CMS consider continuing the delay beyond the period of the public health emergency (PHE). The commenters indicated that hospital claims and cost report data impacted by the COVID–19 pandemic should not be used as the basis of MS–DRG consolidation since utilization may be artificially low during the PHE.

Response: We thank the commenters for their feedback. As stated earlier in this section, we are giving careful consideration to all the recommendations and suggestions we have received in connection with the NonCC subgroup criteria discussion.

Comment: Another commenter expressed concern with regard to how the NonCC subgroup criteria are to be applied. The commenter stated they understood the policy to mean that the NonCC subgroup criteria would only be applied to new requests for MS–DRG splits, not to existing MS–DRGs. The commenter also stated they were unclear when the proposal was finalized since, according to the commenter, CMS would have needed to specify the intent to apply the NonCC subgroup criteria to all existing MS–DRGs versus only for the creation of new MS–DRGs. Additionally, this commenter urged CMS to conduct a full analysis that demonstrates the explanatory power of the proposed new MS–DRGs is an improvement over the current MS–DRGs, similar to the analysis that was performed for the transition from CMS DRGs to MS–DRGs in FY 2008. The commenter indicated that a comprehensive analysis is critical for interested parties to provide meaningful comments.

Response: In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44796), we summarized the discussion pertaining to the NonCC subgroup criteria policy finalized for FY 2021. In that discussion we noted that the application of the NonCC subgroup criteria going forward may result in modifications to certain MS–DRGs that are currently split into three severity levels and result in MS–DRGs that are split into two severity levels. We stated that any proposed modifications to the MS–DRGs would be addressed in future rulemaking consistent with our annual process and reflected in Table 5—Proposed List of Medicare Severity Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay for the applicable fiscal year. As discussed in the proposed rule, we applied the nonCC subgroup criteria to each of the MCC, CC, and NonCC subgroups, in our analysis of the MS–DRG classification requests for FY 2023 that we received by November 1, 2021, as well as any additional analyses that were conducted in connection with those requests. We also note that new requests to subdivide a MS–DRG frequently pertain to existing MS–DRGs which differs from requests to create a new base MS–DRG for which the criteria to create subgroups is subsequently applied. In response to the commenter's recommendation that CMS conduct a full analysis similar to the analysis that was performed for the transition from CMS DRGs to MS–DRGs in FY 2008, we appreciate the commenter's suggestion and will take it under advisement.

Comment: Another commenter who recognized differences between the list of MS–DRGs shown for FY 2022 and FY 2023 requested additional transparency for the data being presented for review and for CMS to consider analyzing data from other databases, such as Medicaid or States, to supplement the MS–DRGs known to have lower volumes among the Medicare population (for example, Obstetric MS–DRGs). This commenter also expressed concern about the potential impact to community hospitals if proposed MS–DRG changes in connection with the NonCC subgroup criteria result in significant MS–DRG redistribution.

Response: We thank the commenter for their feedback. As discussed previously, we intend to conduct a comprehensive analysis of the application of the NonCC subgroup criteria that would be made publicly available for review and comment in connection with any proposed MS–DRG changes for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to delay the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split until FY 2024 or later, and are finalizing for FY 2023 to maintain the current structure of the 41 MS–DRGs that currently have a three-way severity level split.

We are making the FY 2023 ICD–10 MS–DRG GROUPER and Medicare Code Editor (MCE) Software Version 40, the ICD–10 MS–DRG Definitions Manual files Version 40 and the Definitions of Medicare Code Edits Manual Version 40 available to the public on our CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

2. Pre-MDC: MS–DRG 018 Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798 through 44806), we finalized our proposal to assign procedure codes describing CAR T-cell, non-CAR T-cell, and other immunotherapies to Pre-MDC MS–DRG 018 and to revise the title for Pre-MDC MS–DRG 018 to ''Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies'' to reflect this assignment. In that discussion, we noted that a few commenters recommended we continue to work with interested parties on ways to improve the predictability and stability of hospital payments for these complex, novel cell therapies and that we should continue to monitor and assess the appropriateness of therapies assigned to MS–DRG 018, if they continue to be aligned on resource use, and whether additional refinements or MS–DRGs may be warranted in the future.

We also noted that the process of code creation and proposed assignment to the most appropriate MS–DRG exists independently, regardless of whether there is an associated application for a new technology add-on payment for a product or technology submitted for consideration in a given fiscal year. Specifically, requests for a new code(s) or updates to existing codes are addressed through the ICD–10 Coordination and Maintenance Committee meetings, held annually in the spring and fall, where code proposals are presented and the public is provided the opportunity to comment. All codes finalized from the fall meeting are subsequently proposed for assignment under the ICD–10 MS–DRGs through rulemaking. We refer the reader to section II.D.17 of the preamble of this final rule for additional information regarding the ICD–10 Coordination and Maintenance Committee meeting process.

As stated in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28130), there were no requests or proposals for new procedure codes to describe the administration of a CAR T-cell or another type of gene or cellular therapy discussed at the September 14–15, 2021 ICD–10 Coordination and Maintenance Committee meeting. For the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting, there were topics included on the agenda and in the related meeting materials that included proposals for new procedure codes to describe the administration of a CAR T-cell or another type of gene or cellular therapy product. The agenda and related meeting materials for these specific topics are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*.

As stated in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44805) and noted previously, the process of code creation and proposed assignment to the most appropriate MS–DRG exists independently, regardless of whether there is an associated application for a new technology add-on payment for a product or technology submitted for consideration in a given fiscal year. We also clarified that the assignment of a procedure code to a MS–DRG is not dependent upon a product's FDA approval. Similarly, the creation of a code to describe a technology that is utilized in the performance of a procedure or service does not require FDA approval of the technology.

Because the diagnosis and procedure code proposals that are presented at the March meeting for an October 1 implementation (upcoming FY) are not finalized in time to include in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes in association with the proposed rule, as noted in prior rulemaking, we use our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code.

As stated in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28130), in response to commenters' recommendation that we continue to assess the appropriateness of the therapies assigned to Pre-MDC MS–DRG 018, we provided the results of our data analysis using the September 2021 update of the FY 2021 MedPAR file for cases reporting the administration of a CAR T-cell or other immunotherapy in Pre-MDC MS–DRG 018 and the number of cases reporting a secondary diagnosis of Z00.6 (Encounter for examination for normal comparison and control in clinical research program). We noted that if a procedure code that is assigned to the logic for Pre-MDC MS–DRG 018 is not listed it is because there were no cases found. We also noted there were no cases reporting diagnosis code Z00.6 as a principal diagnosis. Our findings are shown in the following table.

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs	Secondary Diagnosis Z00.6
018	All cases	558	16.5	$194,717	185
	XW033C7 - Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	50	13.2	$212,265	16
	XW033M7 - Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	11	14.1	$157,950	4
	XW033N7 - Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	4	11.3	$310,561	1
	XW043C7 - Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	435	16.7	$186,038	152
	XW043M7 - Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7	43	20.3	$264,932	7
	XW043N7 -Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7	15	14.2	$182,700	5

The data show that there is a wide range in the volume of cases (4 cases versus 435 cases), average length of stay (11.3 days versus 20.3 days), and average costs ($157,950 versus $310,561) reporting the administration of CAR T-cell therapies in MS–DRG 018. This is to be expected since these therapies continue to evolve and the ICD–10–PCS coding to identify and describe these therapies also continues to be refined through the ICD–10 Coordination and Maintenance Committee meeting process. As additional claims data becomes available for these therapies, we will continue to evaluate to determine if further modifications to Pre-MDC MS–DRG 018 are warranted.

We noted in the proposed rule that in response to our statement in the FY 2022 IPPS/LTCH PPS final rule that we plan to continue engaging with interested parties on additional options for consideration in this field of cellular and gene therapies, we received additional feedback and suggestions, including recommendations for Town Hall meetings/listening sessions to discuss the interconnectedness of these issues; exploration of what was described as a different set and kind of MS–DRGs that would reward providers for controlling patient care costs, without consideration of product costs outside of their control; and evaluation of the creation and assignment of multiple MS–DRGs for cell and gene therapy cases: one to cover patient care costs, the other to cover product costs across therapeutic product categories.

We stated we appreciated this additional feedback and will continue to consider these issues and suggestions in connection with future rulemaking. We also stated we intend to continue engaging with interested parties by sharing updates from our analysis of claims data as we examine and explore potential refinements for these therapies under the IPPS.

Comment: Several commenters expressed support and appreciation that for FY 2023, CMS proposed to maintain the current structure of Pre-MDC MS–DRG 018 that includes ''Other Immunotherapies'', and to maintain its current methodology used to determine the relative weight. Some commenters acknowledged that it is difficult to predict what the associated costs will be in the future for CAR T-cell and other immunotherapies that remain under development. These commenters urged CMS to consider factors such as new or different side effects and how other therapeutic agents that could be administered simultaneously in connection with these therapies may potentially lead to toxicity, as continued monitoring of resource utilization and data analysis for Pre-MDC MS–DRG 018 occurs. Other commenters commended CMS for its commitment to engage with interested parties as the agency continues to analyze claims data and consider the feedback that has been received to date for these therapies.

Response: We thank the commenters for their support and appreciate the additional feedback on other factors to consider as we continue to monitor and analyze the data for Pre-MDC MS–DRG 018. As noted in prior rulemaking, we have received several suggestions, recommendations, and options pertaining to how CAR T-cell and other immunotherapies may be classified under the IPPS in the future. We intend to further examine the feedback received and maintain transparency in our approach moving forward, with the shared goal of enabling continued access to these and other vital treatments for Medicare beneficiaries.

Comment: Similar to the public comments received in response to the FY 2022 IPPS/LTCH PPS proposed rule, for FY 2023, some commenters again expressed concerns with the non-CAR T-cell therapies and other immunotherapies that may be assigned to Pre-MDC MS–DRG 018 and stated that these potential assignments could lead to fluctuations in the relative weight. A few commenters requested that Pre-MDC MS–DRG 018 be limited to CAR T-cell therapies. Other commenters encouraged CMS to clarify its methodology and criteria for assigning new procedure codes to Pre-MDC MS–DRG 018. Some commenters expressed continued concern with the revision to the title for Pre-MDC MS–DRG 018 that was finalized effective FY

2022 to include ''Other Immunotherapies''.

Response: In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798 through 44806), we provided detailed summaries and responses to these same or similar concerns and comments. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28129 through 28131), we provided an overview of the assignment of new procedure codes to Pre-MDC MS–DRG 018 and reiterated much of the discussion from FY 2022 rulemaking. As stated in prior rulemaking, the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We have not made any changes to our established processes or methodologies for MS–DRG assignment of new procedure codes, including with regard to case assignment to Pre-MDC MS–DRG 018, and we refer the reader to the detailed discussion related to Pre-MDC MS–DRG 018 in the FY 2022 IPPS/LTCH PPS final rule. We note that additional claims data is needed to fully analyze and consider all the recommendations we have received, and to potentially develop alternative proposals with respect to payment for these therapies under the IPPS. There is also uncertainty with regard to the number and types of therapies currently under development or undergoing studies and how soon they will be available. We recognize the concerns that have been expressed by commenters and we are also continuing to assess the reliability and stability of the data in light of the ongoing public health emergency.

Comment: Many commenters expressed appreciation to CMS for providing transparency with the cases reporting the administration of a CAR T-cell or other immunotherapy in the FY 2021 MedPAR claims data for Pre-MDC MS–DRG 018. However, a commenter indicated there was confusion about the coded claims data as presented in the proposed rule since the procedure codes described as new technology group 7 became effective October 1, 2021 (FY 2022), which is one year later than the FY 2021 data that was shown in the table in the preamble of the proposed rule. The commenter requested that CMS provide clarification to help eliminate any additional confusion for readers and interested parties who also analyze the data for these therapies.

Response: We thank the commenters for their support. The FY 2021 MedPAR claims data were regrouped using the proposed FY 2023 MS–DRG classifications, therefore, coded claims data for the procedure codes describing the administration of CAR T-cell and other immunotherapy agents reported in FY 2021 was mapped from the FY 2021 MedPAR coded claims data to the procedure codes that are effective for FY 2023. Specifically, the codes that were effective for FY 2021 and are no longer valid were mapped to the new procedure codes that are valid for FY 2023. We also note, as generally stated in the preamble of the proposed rule each year, the diagnosis and procedure codes from the specified FY MedPAR claims data are grouped through the applicable version of the proposed FY GROUPER. For example, as discussed in section II.E.1. of the preamble of the proposed rule (87 FR 28197), the proposed FY 2023 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2021 MedPAR claims data, grouped through the ICD–10 version of the proposed FY 2023 GROUPER (Version 40).

Comment: A commenter suggested that CMS consider establishing a timeframe that would enable the public to comment on procedure codes that may be assigned to Pre-MDC MS–DRG 018 upon being approved and finalized after the spring ICD–10 Coordination and Maintenance Committee meeting. The commenter stated that currently, because procedure codes that are discussed at the spring ICD–10 Coordination & Maintenance (C&M) Committee meeting do not receive proposed assignments and are not published with the IPPS proposed rule given the timing, there is no opportunity for interested parties to provide feedback to CMS about MS–DRG assignments for new codes, including assignment to MS–DRG–018. The commenter acknowledged the C&M meeting is not the appropriate forum for the public to provide input on MS–DRG assignment, however, because Pre-MDC MS–DRG 018 currently has a limited number of procedure codes assigned to it, the commenter stated that interested parties should have the opportunity to review and comment on potential assignment to Pre-MDC MS–DRG 018. This commenter also maintained that it has a unique relationship with the therapies currently assigned to Pre-MDC MS–DRG 018 as its membership is the predominant specialty society associated with these therapies and has the experience and clinical understanding related to resource utilization associated with the administration of these therapies.

Response: We appreciate the commenter's feedback. As discussed elsewhere in this rule as well as in prior rulemaking, because the procedure code proposals discussed at the Spring ICD–10 Coordination and Maintenance Committee meeting are not finalized in time to include in Table 6B.—New Procedure codes associated with the proposed rule, CMS uses an established process to determine the most appropriate MS–DRG assignment for these new procedure codes for the upcoming fiscal year. While we understand and acknowledge the uniqueness of CAR T-cell, gene, and cellular therapies, we believe it is necessary to further examine how and when we could alter our current methodology and timelines to provide the opportunity for interested parties to submit comments and feedback in the assignment of new procedure codes that are finalized after the spring meeting. We also note, as discussed in the proposed rule (87 FR 28130), all codes finalized from the fall meeting are subsequently proposed for assignment under the ICD–10 MS–DRGs through rulemaking, therefore, interested parties seeking the opportunity to more fully comment on potential MS–DRG assignment(s) have the opportunity to submit requests for consideration of proposed new procedure codes in association with these therapies to be discussed at the fall meeting versus the spring meeting. Alternatively, interested parties may use current coding information as shown in the ICD–10 Coordination and Maintenance Committee meeting materials to consider the potential MS–DRG assignments for any procedure codes that may be finalized after the March meeting and submit public comments for consideration.

As noted in the proposed rule, for the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting there were two topics included on the agenda and in the related meeting materials that included proposals for new procedure codes to describe the administration of a CAR T-cell or another type of gene or cellular therapy product. The two topics are Administration of afamitresgene autoleucel (afami-cel), a specific peptide enhanced affinity receptor (SPEAR) T-cell therapy and Administration of Tabelecleucel (tab-cel®), an allogeneic Epstein-Barr virus (EBV)-specific T-cell immunotherapy, both of which were approved for new procedure codes following the March meeting. We refer the reader to the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional detailed information regarding these code requests.

Because the diagnosis and procedure code proposals that are presented at the March ICD–10–CM Coordination and Maintenance Committee meeting for an October 1 implementation (upcoming FY) are not finalized in time to include in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes in association with the proposed rule, as we have noted in prior rulemaking, we use our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code. As shown in Table 6B.—New Procedure Codes associated with this final rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*, new procedure codes for these two therapies have been finalized for assignment to Pre-MDC MS–DRG 018 effective with discharges on and after October 1, 2022 (FY 2023).

We appreciate the public comments we received, and, as noted, will continue to evaluate the recommendations and options provided by commenters related to these therapies as well as to monitor the available claims data.

3. MDC 01 (Diseases and Disorders of the Nervous System)

a. Laser Interstitial Thermal Therapy (LITT)

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44812 through 44814), we finalized the reassignment of 31 ICD–10–PCS procedure codes describing laser interstitial thermal therapy (LITT) of various body parts to more clinically appropriate MS–DRGs, as shown in Table 6P.2b associated with the FY 2022 IPPS/LTCH PPS final rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*, including the reassignment of procedure codes D0Y0KZZ (Laser interstitial thermal therapy of brain) and D0Y1KZZ (Laser interstitial thermal therapy of brain stem), which were reassigned from MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator), MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC), and MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC and without CC/MCC, respectively).

We also finalized the redesignation of these two LITT procedures (codes D0Y0KZZ and D0Y1KZZ) and the reassignment from extensive O.R. procedures in MS–DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to non-extensive O.R. procedures in MS–DRGs 987, 989, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) (86 FR 44889).

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28131), for FY 2023, we received two requests from the manufacturers of the LITT technology (Medtronic and Monteris® Medical) to reverse the MS–DRG reassignment for the ICD–10 procedure codes that identify LITT of the brain and brain stem (codes D0Y0KZZ and D0Y1KZZ) from the MS–DRGs for peripheral, cranial nerve and other nervous system procedures (MS–DRGs 040, 041, and 042) back to the MS–DRGs for craniotomy and endovascular procedures (MS–DRGs 023, 024, 025, 026, and 027). The first requestor acknowledged that the technique utilized in the performance of LITT procedures for the brain and brain stem are minimally invasive and do not involve a craniotomy however, the requestor also stated the procedures assigned to MS–DRGs 025, 026, and 027 are not exclusive to craniotomies. The requestor further stated that these LITT procedures involve a twist drill or burr hole and are similar to other non-craniotomy procedures in MS–DRGs 025, 026, and 027 including radioactive elements and neurostimulator leads that involve inserting these devices into the brain.

In its review of the other procedures assigned to MS–DRGs 040, 041, and 042, the requestor stated that there are distinct clinical differences between the invasiveness of LITT that involves instrumentation being placed deeply within the brain tissue and the non-invasiveness of stereotactic radiosurgery that does not involve entering the brain with instrumentation. The requestor also indicated LITT utilizes a different modality via direct thermal ablation compared to stereotactic radiosurgery that utilizes externally-generated ionizing radiation.

The requestor performed its own data analysis for LITT procedures of the brain and brain stem using MedPAR data from FY 2019 through FY 2022 impact files. According to the requestor, its findings demonstrate that the costs of the cases reporting LITT of the brain or brain stem are better aligned with MS–DRGs 025, 026, and 027 compared to MS–DRGs 040, 041, and 042.

The second requestor similarly discussed the steps and resources involved in the performance of LITT procedures for the brain and brain stem, provided its detailed analysis on the indications for LITT (brain tumors and epileptic foci), compared LITT to other procedures in MS–DRGs 025, 026, and 027 and stated that the majority of the procedures currently assigned to MS–DRGs 040, 041, 042 are not performed for the treatment of brain cancer or epilepsy. The requestor stated that the LITT procedure is on the inpatient only list and is only performed on Medicare beneficiaries in the inpatient hospital setting. The requestor provided the top 10 principal diagnoses associated with LITT of brain cases it found based on its analysis, and identified the diagnoses for which there were less than 10 cases with an asterisk, as reflected in the following table.

ICD-10-CM Code	Description	Cases
C79.31	Secondary malignant neoplasm of brain	39
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus	17
C71.9	Malignant neoplasm of brain, unspecified	13
C71.1	Malignant neoplasm of frontal lobe	*
C71.2	Malignant neoplasm of temporal lobe	*
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus	*
I67.89	Other cerebrovascular disease	*
G40.919	Epilepsy, unspecified, intractable, without status epilepticus	*
G40.804	Other epilepsy, intractable, without status epilepticus	*
C71.3	Malignant neoplasm of parietal lobe	*

The requestor asserted that the statement in the FY 2022 IPPS/LTCH PPS final rule that the technique to perform the LITT procedure on brain and brain stem structures is considered minimally invasive and does not involve a craniotomy, and that therefore, continued assignment to the craniotomy MS–DRGs is not clinically appropriate, mischaracterizes both the LITT procedures and universe of services assigned to MS–DRGs 023 through 027. The requestor acknowledged that the craniotomy procedures listed in the logic for MS–DRGs 023 through 027 include open procedures but stated the logic also lists less invasive procedures including percutaneous and percutaneous endoscopic procedures. The requestor asserted that open procedures are a minority of the ICD–10–PCS codes assigned to these MS–DRGs.

In addition, the requestor stated that LITT and craniotomy are in fact very clinically similar; in that both procedures are intended to remove and destroy the targeted tumor and lesion with a different surgical tool used (scalpel versus heated ablation probe). According to the requestor, brain LITT procedures involve insertion of laser probes into the brain which requires opening both the skull and dura, similar to a craniotomy. The requestor also stated that craniotomy and LITT share several procedural characteristics and provided the following list.

- Require an operating room;
- Performed under general anesthesia;
- Require creation of burr holes and invasive skull fixation;
- Require a sterile field, incision, opening of the skull and dura;
- Cause tissue to be immediately destroyed or excised;
- Carry a risk of immediate intracranial bleeding;
- Require closure of the scalp wound;
- Risk intracranial infection; and
- Require a hospital stay of one or more nights.

In contrast, the requestor stated that procedures assigned to MS–DRGs 040, 041, and 042 are primarily nerve procedures or excision or detachment procedures performed on parts of the body other than the head, including the upper and lower extremities. According to the requestor, none of the procedures in MS–DRGs 040, 041, and 042 require drilling into the patient's skull, a step which is integral to LITT. The requestor provided the following top 10 principal diagnoses associated with cases it found in MS–DRGs 040, 041, and 042 during its analysis and stated that most of the procedures assigned to MS–DRGs 040, 041, and 042 are not typically performed in the treatment of brain cancer or epilepsy.

ICD-10-CM Code	Description	Cases
I63.9	Cerebral infarction, unspecified	1,928
I63.40	Cerebral infarction due to embolism of unspecified cerebral artery	610
I63.89	Other cerebral infarction	489
G45.9	Transient cerebral ischemic attack, unspecified	456
I63.412	Cerebral infarction due to embolism of left middle cerebral artery	378
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy	371
I63.411	Cerebral infarction due to embolism of right middle cerebral artery	341
I63.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery	335
C79.31	Secondary malignant neoplasm of brain	326
I63.81	Other cerebral infarction due to occlusion or stenosis of small artery	271

However, the requestor stated an exception is stereotactic radiosurgery (SRS) procedures performed on the brain and brain stem that are assigned to MS–DRGs 040, 041, and 042 and are used to treat brain cancer. According to the requestor, craniotomy, LITT and SRS are all image-guided procedures used to treat a variety of brain disorders including tumors and epilepsy, although it stated that is where any similarity between LITT and SRS ends and where the procedural similarities between craniotomy and LITT begin.

The requestor stated SRS is a non-invasive procedure that gradually destroys or inactivates tissues in or around the brain and is typically performed on an outpatient basis while inpatient SRS treatment is rare. According to the requestor, SRS does not require an operating room, is rarely done under general anesthesia (children and highly claustrophobic individuals being an exception), and does not require (but can use) rigid skull fixation. In addition, the requestor stated that because it is non-invasive, there is no need for a sterile field, incision, opening/closing of the skull, opening/closing of the dura, suturing/stapling the wound, and produces essentially no risk of immediate intracranial bleeding or delayed infection. According to the requestor, LITT is much more invasive than SRS using a head frame and involves and requires the same surgical skill and hospital resources as craniotomies.

In the proposed rule we noted that following the submission of the two FY 2023 MS–DRG classification change requests for LITT, these same two requestors (the manufacturers of the LITT technology) submitted a joint code proposal requesting an overall change to how LITT is classified within the ICD–10–PCS classification and for consideration as an agenda topic to be discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting. The proposal was presented and discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting. We referred the reader to the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional detailed information regarding the request, including a recording of the discussion and the related meeting materials. Public comments in response to the code proposal were due by April 8, 2022.

Because the diagnosis and procedure code proposals that are presented at the March ICD–10–CM Coordination and Maintenance Committee meeting for an October 1 implementation (upcoming FY) are not finalized in time to include in Table 6A. —New Diagnosis Codes and Table 6B.—New Procedure Codes in association with the proposed rule, as we have noted in prior rulemaking and discuss further in this section, we use our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code. Under this established process, the MS–DRG assignment for the upcoming fiscal year for any new diagnosis or procedure codes finalized after the March meeting would be reflected in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes associated with the final rule for that fiscal year. However, as stated in the proposed rule, in light of the unique circumstances relating to these procedures, for which there was a pending proposal to reclassify LITT within ICD–10–PCS and for new procedure codes discussed at the March meeting, as well as an MS–DRG reclassification request to reassign the existing codes describing these procedures, we addressed in this section first, the code proposal discussed at the March meeting and the possible MS–DRG assignments for any new codes that may be approved, and then secondly, the requested reassignment of the existing codes, in the event the new codes are not approved.

To summarize, as discussed at the March meeting, the code proposal was to reclassify LITT procedures from the Radiation Therapy section of ICD–10–PCS (Section D) to the Medical and Surgical section of ICD–10–PCS. Specifically, the proposal was to reclassify LITT procedures to the root operation Destruction. In ICD–10–PCS, the root operation Destruction is defined as physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent. According to the requestors, LITT is misclassified to section D-Radiation Therapy in ICD–10–PCS possibly because of terminology that was used for predicate devices, whose indications included the phrase ''interstitial irradiation or thermal therapy'' in describing LITT's method of action. The requestors stated LITT is thermal therapy, destroying soft tissue using heat generated by a laser probe at the target site and that the LITT procedure does not use ionizing radiation, which is what the term ''radiation'' commonly refers to in the general medical sense. The requestors also stated that by itself, radiation is a broad term and provided an example that the spectrum of electromagnetic radiation technically encompasses low energy non-ionizing radio waves, microwaves, and infrared to high energy ionizing X-rays and gamma rays while ionizing radiation creates ions in the cells it passes through by removing electrons, a process which kills or alters the cells over time.

The requestors further stated that only certain medical uses of radiation are classified to section D-Radiation Therapy. For instance, section D-Radiation Therapy categorizes treatments using ionizing radiation, including beam radiation, brachytherapy, and stereotactic radiosurgery. All of these deliver concentrated ionizing radiation to eradicate abnormal cells, most commonly neoplasms. Other treatments classified to section D-Radiation Therapy, such as hyperthermia, are used as adjuncts to ionizing radiation. The requestors asserted that while LITT eradicates abnormal cells, it does so with heat, not ionizing radiation and rather than a radiation therapy procedure, LITT is a surgical procedure. According to the requestors, LITT would be more appropriately classified as an ablation procedure with the root operation Destruction.

As stated in the proposed rule, the original request for a new code(s) to describe the LITT technology was initially discussed at the September 24–25, 2008 ICD–9–CM Coordination and Maintenance Committee meeting. At that time, the requestor sought an April 1, 2009 implementation date. Public comments opposed an April 1, 2009 implementation date, therefore, effective October 1, 2009 (FY 2010), ICD–9–CM procedure codes were created to identify procedures performed utilizing the LITT technology. The following table lists the ICD–9–CM procedure codes describing LITT and their respective MDC and MS–DRG assignments under the ICD–9 based MS–DRGs. We refer the reader to the ICD–9 and ICD–10 MS–DRG Definitions Manual Files V33 (available via the

internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download-Items/FY2016-Final-Rule-Correction-Notice-Files* in the Downloads section) for complete documentation of the GROUPER logic for ICD–9.

ICD-9-CM Procedure Code	Description	MDC	MS-DRG
17.61	Laser interstitial thermal therapy [LITT] of lesion or tissue of brain under guidance	MDC 01	023-027
17.62	Laser interstitial thermal therapy [LITT] of lesion or tissue of head or neck under guidance	MDC 10	625-627
		MDC 17	820-822
		MDC 17	826-828
17.63	Laser interstitial thermal therapy [LITT] of lesion or tissue of liver under guidance	MDC 06	356-358
		MDC 07	405-407
17.69	Laser interstitial thermal therapy [LITT] of lesion or tissue of other and unspecified site under guidance	MDC 04	163-165
		MDC 09	584-585
		MDC 12	715-718
		MDC 17	820-822
		MDC 17	826-828

The requestors maintain that although LITT was used to treat a variety of anatomic sites when it was first introduced, its current primary use is intracranial, specifically to treat brain tumors and epileptic foci. However, the requestors stated it is also used to treat radiation necrosis, an inflammatory response from prior treatment with ionizing radiation.

We noted in the proposed rule that currently, in the U.S., there are only two LITT systems in use, Visualase™ MRI-Guided Laser Ablation (Medtronic) and the Neuroblate® System (Monteris® Medical). The requestors also stated that over the last six years, the Indications for Use (IFU) for one of the two U.S. approved LITT technologies (Neuroblate®) has been updated to reflect the system's current use in the brain and to align with the intended neurosurgical patient population. The requestor indicated applications in the spine are also anticipated in the future within the central nervous system.

As previously noted, the deadline for receipt of public comments for the proposed reclassification of LITT procedures that was presented at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting along with the corresponding proposal for new procedure codes was April 8, 2022, and the final code decisions on these proposals were not yet available for inclusion in Table 6B.—New Procedure Codes associated with the FY 2023 IPPS/LTCH PPS proposed rule. However, as discussed in prior rulemaking (86 FR 44805), codes that are finalized after the March meeting are reviewed and subject to our established process of initially reviewing the predecessor codes MS–DRG assignment and designation, while considering other relevant factors (for example, severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition) as previously described. The codes that are finalized after the March meeting are specifically identified with a footnote in Tables 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes that are made publicly available in association with the final rule via the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*. The public may provide feedback on these finalized assignments, which is then taken into consideration for the following fiscal year.

We stated in the proposed rule that the MS–DRG assignment for any new procedure codes describing LITT, if finalized following the March meeting, would be reflected in Table 6B.—New Procedure Codes associated with the final rule for FY 2023. However, in light of the unique circumstances with respect to these procedures, for which there was both a proposal for reclassifying LITT from the Radiation Therapy section of the procedure code classification to the Medical/Surgical section with new ICD–10–PCS procedure code(s) and a separate MS–DRG reclassification request on the existing procedure codes, we provided the opportunity for public comment on possible MS–DRG assignments for the requested new procedure codes describing LITT that may apply based on the application of our established process and analysis, in the event the new codes were finalized for FY 2023. We also noted that while we discussed the potential MS–DRG assignments for new procedure codes describing LITT, interested parties may use current coding information to consider the potential MS–DRG assignments for any other procedure codes that may be finalized after the March meeting and submit public comments for consideration. Specifically, in the ICD–10 Coordination and Maintenance Committee meeting materials (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*), for each procedure code proposal we provide the current coding that is applicable within the classification and that should be reported in the absence of a more unique code, or until such time a new code is created and becomes effective. The procedure code(s) listed in current coding are generally, but not always, the same code(s) that are considered as the predecessor code(s) for purposes of MS–DRG assignment. As previously noted, our process for determining the MS–DRG assignment for a new procedure code does not automatically result in the new procedure code being assigned to the

same MS–DRG or having the same designation (O.R. versus Non-O.R.) as the predecessor code. However, this current coding information can be used in conjunction with the GROUPER logic, as set forth in the ICD–10 MS–DRG Definitions Manual and publicly available via the internet on our CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* to review the MS–DRG assignment of the current code(s) and examine the potential MS–DRG assignment of the proposed code(s), to assist in formulating any public comments for submission to CMS for consideration.

We noted in the proposed rule that, unlike the typical code request for a new or revised procedure code that involves a new technology or a new approach to performing an existing procedure, the circumstances for this particular request are distinct in that the code request would reclassify LITT within the ICD–10–PCS classification from section D—Radiation Therapy to the root operation Destruction in the Medical and Surgical section of ICD–10–PCS. Therefore, in light of the unique considerations with respect to the requested reclassification of the LITT procedures in connection with the pending code proposal, we stated we believe it was appropriate to utilize the assignments and designations of the procedure codes describing Destruction of the respective anatomic body site as predecessor codes rather than the current codes describing LITT from the Radiation Therapy section of ICD–10–PCS in considering potential MS–DRG assignment for the requested new LITT procedure codes.

As previously discussed, under our established process for determining the MS–DRG assignment for newly approved procedure codes, we examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment for the new codes. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. As we have noted in prior rulemaking, this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code.

Applying this established review process to the proposed codes for the LITT procedures, we stated we believe that, based on the predecessor codes, and as previously noted, the potential assignments and designations would align with the assignments and designations of the procedure codes describing Destruction of the respective anatomic body site. For example, as discussed in the preamble of the proposed rule and earlier in this section of this final rule, the code request involved reclassifying LITT procedures from section D—Radiation Therapy to the root operation Destruction in the Medical and Surgical section of ICD–10–PCS. The root operation Destruction is appropriate to identify and report procedures, such as ablation, that are performed on various body parts. The code request also involved creating what is referred to as a qualifier value, to uniquely describe LITT as the modality. The qualifier value is the seventh character or digit, in a valid ICD–10–PCS procedure code.

We presented the following ICD–10–PCS table in the proposed rule, which illustrates an example of the proposed procedure codes for LITT of the brain and brain stem, and cervical, thoracic, and lumbar spinal cord body parts, including the qualifier value that was presented and discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting.

Section	**0** Medical and Surgical
Body System	**0** Central Nervous System and Cranial Nerves
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	Approach	Device	Qualifier
0 Brain **W** Cervical Spinal Cord **X** Thoracic Spinal Cord **Y** Lumbar Spinal Cord	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**ADD 3** Laser Interstitial Thermal Therapy **Z** No Qualifier

We noted in the proposed rule that the code proposal presented only provided the body part value 0 Brain, for reporting any LITT procedures performed on the brain, as well as, the brain stem, consistent with the current available body part option in Table 005, Destruction of Central Nervous System and Cranial Nerves, where the predecessor code is located. We also noted that the predecessor code(s) and associated MS–DRG assignments for the proposed new procedure code(s) describing LITT of the brain and spinal cord under MDC 01 are identified as follows.

ICD-10-PCS Code	Description	MS-DRG
00500ZZ	Destruction of brain, open approach	023-027
00503ZZ	Destruction of brain, percutaneous approach	
00504ZZ	Destruction of brain, percutaneous endoscopic approach	
005W0ZZ	Destruction of cervical spinal cord, open approach	028-030
005W3ZZ	Destruction of cervical spinal cord, percutaneous approach	
005W4ZZ	Destruction of cervical spinal cord, percutaneous endoscopic approach	
005X0ZZ	Destruction of thoracic spinal cord, open approach	
005X3ZZ	Destruction of thoracic spinal cord, percutaneous approach	
005X4ZZ	Destruction of thoracic spinal cord, percutaneous endoscopic approach	
005Y0ZZ	Destruction of lumbar spinal cord, open approach	
005Y3ZZ	Destruction of lumbar spinal cord, percutaneous approach	
005Y4ZZ	Destruction of lumbar spinal cord, percutaneous endoscopic approach	

As shown in the table, the procedure codes describing destruction of brain with an open, percutaneous or percutaneous endoscopic approach are assigned to MS–DRGs 023 through 027 (craniotomy and endovascular procedures) and the procedure codes describing destruction of cervical, thoracic or lumbar spinal cord with an open, percutaneous or percutaneous endoscopic approach are assigned to MS–DRG 028 (Spinal Procedures with MCC), MS–DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), and MS–DRG 030 (Spinal Procedures without CC/MCC).

We referred the reader to Table 6P.2a associated with the proposed rule (and available via the internet at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*) to review the potential MDCs, MS–DRGs, and O.R. versus Non-O.R. designations identified based on this analysis of the proposed new procedure codes describing LITT as presented and discussed at the meeting. We noted that Table 6P.2a also includes the predecessor codes that we utilized to inform this analysis. We stated that if finalized, the new procedure codes would be included in the FY 2023 code update files that are made available in late May/early June via the internet on the CMS website at: *https://www.cms.gov/medicare/coding/icd10*. Additionally, we noted that if finalized, the new procedure codes describing LITT would be displayed in Table 6B.—New Procedure Codes, and the existing codes describing LITT would be deleted and reflected in Table 6D.—Invalid Procedure Codes, in association with the FY 2023 IPPS/LTCH PPS final rule. We referred the reader to section II.D.14. of the preamble of the proposed rule for further information regarding the files.

We note that the proposal to reclassify LITT procedures of the brain, brain stem and other anatomic sites in ICD–10–PCS that was discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting was approved and new procedure codes describing LITT of the brain and other anatomic sites were finalized as reflected in the FY 2023 ICD–10–PCS Code Update files that were made publicly available via the internet on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10* on May 26, 2022. We also note that the new procedure codes effective October 1, 2022 describing LITT of the brain and other anatomic sites are displayed in Table 6B.—New Procedure Codes, and the existing codes describing LITT of the brain, brain stem, and other anatomic sites that are being deleted effective October 1, 2022 are reflected in Table 6D.—Invalid Procedure Codes, in association with this FY 2023 IPPS/LTCH PPS final rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. Below we summarize the public comments we received and present our responses.

Comment: Commenters expressed appreciation that the proposal to reclassify LITT procedures in ICD–10–PCS that was discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting was approved and new procedure codes have been finalized as reflected in the FY 2023 ICD–10–PCS Code Update files that were made publicly available via the internet on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10* on May 26, 2022. Commenters also indicated it is appropriate to utilize procedure codes with the root operation Destruction as the predecessor codes for MS–DRG assignment of the new LITT procedure codes for all the anatomic body sites. Several commenters expressed support for the assignment of cases reporting new procedure codes for LITT of brain (includes brain stem) from MS–DRGs 040, 041, and 042 to MS–DRGs 025, 026 and 027 and urged CMS to finalize this assignment. The commenters commended CMS for recognizing the unique clinical circumstances related to LITT procedures of the brain as being more appropriately aligned with MS–DRGs 025, 026 and 027. A commenter acknowledged that the new procedure codes for LITT of brain had not yet been finalized at the time of the development of the proposed rule and therefore, were not reflected in the V40 Test GROUPER software, however, the commenter encouraged CMS to ensure the final V40 GROUPER logic reflects the new procedure codes for LITT of brain and assignment to MS–DRGs 025, 026 and 027.

Response: We thank the commenters for their support. In addition to the new procedure codes describing LITT being made publicly available in the FY 2023 ICD–10–PCS Code Update files via the internet on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10*, we note that, as previously stated, the new procedure codes are also reflected in Table 6B.—New Procedure Codes, in association with this final rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* with their finalized MS–DRG assignments. As shown in the table, procedure codes describing LITT of brain (root operation Destruction), are assigned to MS–DRGs 025, 026 and 027 for FY 2023. This assignment is also reflected in the final V40 GROUPER logic. Existing procedure

codes D0Y0KZZ (Laser interstitial thermal therapy of brain) and D0Y1KZZ (Laser interstitial thermal therapy of brain stem) will be deleted effective October 1, 2022, as reflected in Table 6D.—Invalid Procedure Codes, in association with this final rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

As discussed in the proposed rule and previously discussed in this final rule, we also received requests to reassign the existing ICD–10 procedure codes that identify LITT of the brain and brain stem (codes D0Y0KZZ and D0Y1KZZ). We stated in the proposed rule that in the event there is not support for the proposed reclassification of LITT procedures and the corresponding new procedure codes as presented at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting, we were also providing the results of our analysis of these existing codes and our proposed MS–DRG assignments for FY 2023, if those existing codes are retained.

In the proposed rule we stated that we examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 023, 024, 025, 026, and 027, in addition to MS–DRGs 040, 041, and 042 for cases reporting LITT of the brain (code D0Y0KZZ) or brain stem (code D0Y1KZZ). We noted that if a procedure code is not listed it is because there were no cases found reporting that procedure code. Our findings are shown in the following tables.

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
23	All Cases	11,599	10.1	$45,134
	D0Y0KZZ	1	15	$60,994
	All other cases	11,598	10.1	$45,133
24	All Cases	4,391	5.2	$31,759
25	All Cases	19,586	9	$35,956
	D0Y0KZZ	77	5.6	$27,148
	All other cases	19,509	9	$35,991
26	All Cases	6,956	5.1	$24,566
	D0Y0KZZ	25	2.6	$24,741
	All other cases	6,931	5.1	$24,565
27	All Cases	7,323	2.4	$20,498
	D0Y0KZZ	20	2.1	$34,874
	All other cases	7,303	2.4	$20,459

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
40	All Cases	3,547	9.9	$30,212
	D0Y0KZZ	14	8.1	$40,458
	All other cases	3,533	9.9	$30,171
41	All Cases	4,958	5	$19,090
	D0Y0KZZ	16	3.4	$23,278
	D0Y1KZZ	1	1	$10,222
	All other cases	4,942	5	$19,076
42	All Cases	1,667	2.9	$15,451
	D0Y0KZZ	24	1.7	$22,426
	D0Y1KZZ	1	2	$32,668
	All other cases	1,642	2.9	$15,325

As shown, we found a total of 123 cases reporting LITT of the brain across MS–DRGs 023, 025, 026, and 027. There were no cases found in MS–DRG 024. The cases reporting LITT of the brain grouped to these MS–DRGs because another O.R. procedure that is assigned to the respective MS–DRG was also reported. We referred the reader to Table 6P.2b in association with the proposed rule for the list of the other

O.R. procedures we identified that were also reported with LITT of the brain.

For MS–DRGs 040, 041, and 042, we found a total of 54 cases reporting LITT of the brain and 2 cases reporting LITT of the brain stem. While the average costs of the cases reporting LITT of the brain were higher compared to all the cases in their respective MS–DRGs, the average length of stay was shorter. For example, the data demonstrates a shorter average length of stay (8.1 days versus 9.9 days) and higher average costs ($40,458 versus $30,212) for the 14 cases reporting LITT of brain in MS–DRG 040 compared to all the cases in MS–DRG 040. There were no cases found to report LITT of brain stem in MS–DRG 040. For MS–DRG 041, we found 16 cases reporting LITT of brain with an average length of stay of 3.4 days and average costs of $23,278 and 1 case reporting LITT of brain stem with an average length of stay of 1 day and average costs of $10,222. The average length of stay for all the cases in MS–DRG 041 is 5 days with average costs of $19,090. The data demonstrates a shorter average length of stay (3.4 days and 1 day, respectively, versus 5 days) for the 16 cases reporting LITT of brain and the 1 case reporting LITT of brain stem. The data also demonstrates higher average costs ($23,278 versus $19,090) for the 16 cases reporting LITT of brain, and lower average costs for the 1 case reporting LITT of brain stem ($10,222 versus $19,090), as compared to the average costs of all cases in MS–DRG 041. For MS–DRG 042, we found 24 cases reporting LITT of brain with an average length of stay of 1.7 days and average costs of $22,426 and 1 case reporting LITT of brain stem with an average length of stay of 2 days and average costs of $32,668. The average length of stay for all the cases in MS–DRG 042 is 2.9 days with average costs of $15,451. The data demonstrates a shorter average length of stay (1.7 days and 2 days, respectively, versus 2.9 days) for the 24 cases reporting LITT of brain and the 1 case reporting LITT of brain stem. The data also demonstrate higher average costs ($22,426 and $32,668, respectively versus $15,451) for the 24 cases reporting LITT of brain and the 1 case reporting LITT of brain stem, compared to all the cases in MS–DRG 042.

We noted in the proposed rule that, based on the findings from our analysis, we considered whether other factors, such as the reporting of secondary MCC and CC diagnoses, may have contributed to the higher average costs for these cases. Specifically, we conducted additional analyses of the claims data from the September 2021 update of the FY 2021 MedPAR file to determine what secondary MCC diagnoses were also reported for the 14 cases reporting LITT of brain in MS–DRG 040 and what secondary CC diagnoses were reported for the 17 cases (16 for LITT of brain and 1 for LITT of brain stem) in MS–DRG 041. Our findings are shown in the following tables.

Secondary MCC Diagnoses Reported with LITT of Brain in MS-DRG 040				
ICD-10-CM Code as Secondary Diagnosis	**Description**	**Frequency of Diagnosis**	**Average Length of Stay**	**Average Costs**
D61.810	Antineoplastic chemotherapy induced pancytopenia	1	9	$59,102
G93.5	Compression of brain	6	12.2	$56,313
G93.6	Cerebral edema	11	9.3	$43,788
I61.1	Nontraumatic intracerebral hemorrhage in hemisphere, cortical	1	48	$80,745
J69.0	Pneumonitis due to inhalation of food and vomit	2	28	$60,889
J96.01	Acute respiratory failure with hypoxia	3	17	$41,486

Secondary CC Diagnoses Reported with LITT of Brain and Brain Stem in MS-DRG 041				
ICD-10-CM Code as Secondary Diagnosis	**Description**	**Frequency of Diagnosis**	**Average Length of Stay**	**Average Costs**
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung	1	1	$9,755
C79.51	Secondary malignant neoplasm of bone	1	29	$22,347
D61.818	Other pancytopenia	1	1	$29,883
D62	Acute posthemorrhagic anemia	1	2	$9,101
E22.2	Syndrome of inappropriate secretion of antidiuretic hormone	1	2	$17,940
E44.0	Moderate protein-calorie malnutrition	1	1	$29,883
F33.0	Major depressive disorder, recurrent, mild	1	8	$57,999
F33.1	Major depressive disorder, recurrent, moderate	1	1	$20,461
F84.0	Autistic disorder	1	1	$12,450
G40.89	Other seizures	1	1	$12,109
G40.919	Epilepsy, unspecified, intractable, without status epilepticus	1	1	$34,287
G81.91	Hemiplegia, unspecified affecting right dominant side	1	2	$17,940
G81.94	Hemiplegia, unspecified affecting left nondominant side	1	8	$57,999
G96.01	Cranial cerebrospinal fluid leak, spontaneous	1	1	$25,514
H47.10	Unspecified papilledema	1	29	$22,347
I16.1	Hypertensive emergency	1	1	$30,372
I42.8	Other cardiomyopathies	1	1	$55,389
I48.21	Permanent atrial fibrillation	1	1	$29,883
I50.22	Chronic systolic (congestive) heart failure	1	1	$55,389
I50.32	Chronic diastolic (congestive) heart failure	1	1	$29,883
I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side	1	1	$12,109
N39.0	Urinary tract infection, site not specified	2	15.5	$16,866
Q01.9	Encephalocele, unspecified	1	2	$9,101
Q04.8	Other specified congenital malformations of brain	2	1	$13,925
R47.01	Aphasia	3	3.3	$28,841
Z68.42	Body mass index [BMI] 45.0-49.9, adult	1	1	$10,222
Z94.0	Kidney transplant status	1	1	$25,514

We noted that we did not find any other O.R. procedures reported on the claims in addition to the procedures for LITT of brain or brain stem for MS–DRGs 040, 041 and 042.

The data shows that at least one of the listed secondary MCC diagnoses was reported with each claim for LITT of brain identified in MS–DRG 040 and the average length of stay for these cases ranged from 9 days to 48 days and the average costs of these cases ranged from $41,486 to $80,745. We note that this data reflects the frequency with which each of the listed diagnoses was reported on a claim with LITT of brain. Therefore, multiple MCCs from this list of diagnoses may have been reported on a single claim. In addition, while the logic for case assignment to MS–DRG 040 requires at least one secondary MCC diagnosis, we conducted additional detailed analyses for MS–DRG 040, as shown in Table 6P.2f, to determine whether there were also secondary CC diagnoses reported in conjunction with one or more of the listed MCC diagnoses that may be contributing to the higher average costs for cases reporting LITT of brain in MS–DRG 040 in comparison to all the cases in MS–DRG 040. We found that 6 of the 14 cases reporting at least one or more secondary MCC diagnosis also reported one or more secondary CC diagnosis, which would appear to support that the severity of illness for these patients, as identified by the secondary MCC and CC diagnoses, may be more directly related to the higher average costs for these patients than the LITT procedure itself.

Similarly, the data for MS–DRG 041 show the frequency with which each of the listed secondary CC diagnoses was reported with LITT of brain or brain stem. Results from the analysis for the 17 cases (16 for LITT of brain and 1 for LITT of brain stem) show the average length of stay for these cases ranged from 1 day to 29 days and the average costs ranged from $9,101 to $57,999. These data analysis findings for MS–DRG 041 also appear to support our belief that the severity of illness for

these patients, as identified by the listed secondary CC diagnoses, may be more directly related to the higher average costs for these patients than the LITT procedure itself.

As stated in the proposed rule and previously in this final rule, we did not find any other O.R. procedures reported on the claims in addition to the procedures for LITT of brain or brain stem for MS–DRGs 040, 041 and 042. Since the logic for case assignment to MS–DRG 042 is not based on the reporting requirement of any CC or MCC diagnoses, we conducted a detailed analysis of the claims data to determine what other factors may be contributing to the higher average costs and shorter average length of stay for these cases in comparison to all the cases in MS–DRG 042. We refer the reader to Table 6P.2g associated with the proposed rule for the findings from our analysis. As shown in the data, the majority of the cases (15 of 25) had a principal diagnosis of epilepsy, 8 cases had a principal diagnosis related to malignant neoplasm of the brain or brain structures, 1 case had a principal diagnosis of hemangioma of intracranial structures and 1 case had a principal diagnosis of unspecified convulsions. The data also demonstrate that 16 of the 25 cases reported in MS–DRG 042 include patients who were under the age of 65, with ages ranging from 32 years old to 64 years old. We note that patients diagnosed with epilepsy are eligible for coverage since it is a condition that qualifies under certain criteria. It is not entirely clear if the age of these patients had any impact on the average length of stay since the average length of stay of the 24 cases reporting LITT of brain was 1.7 days and the 1 case reporting LITT of brain stem was 2 days.

As stated previously, the logic for case assignment to MS–DRG 042 is not dependent on the reporting of any CC or MCC diagnoses, however, based on the diagnoses reflected in the claims data for MS–DRG 042, it is possible that conditions such as obesity and chronic conditions requiring the long-term use of certain therapeutic agents may be contributing factors to the consumption of resources, separately from the LITT procedure. We found 17 of the 25 cases reporting LITT of brain or brain stem to also report one or both of these conditions.

We also reviewed the number of cases of LITT of the brain or brain stem procedures reported in the data since the transition to ICD–10. Specifically, we examined the claims data for cases reporting LITT of brain or brain stem as a standalone procedure or with another procedure in the FY 2016 through FY 2021 MedPAR data files across all MS–DRGs. The findings from our analysis are shown in table 6P.2e associated with the proposed rule.

The data demonstrates that since the implementation of ICD–10, a shift in the reporting of LITT of brain and brain stem procedures has occurred. For example, the FY 2016, FY 2017 and FY 2018 MedPAR data reflect that the number of cases for which LITT of brain or brain stem procedures were reported as a standalone procedure is higher in comparison to the number of cases reported with another procedure. Conversely, the FY 2019, FY 2020, and FY 2021 MedPAR data reflect that the number of cases for which LITT of brain or brain stem procedures were reported as a standalone procedure is lower in comparison to the number of cases reported with another procedure. The data also reflect that the average length of stay is shorter and the average costs are lower for cases reporting LITT of brain or brain stem as a standalone procedure in comparison to the average length of stay and average costs for cases reported with another procedure across the FY 2016 through FY 2021 MedPAR data files. Lastly, the data demonstrate that overall, the number of cases for which LITT of brain or brain stem procedures was performed had remained fairly stable at over 100 cases with increases in the FY 2017, FY 2020 and FY 2021 MedPAR data files of 156, 154 and 185 cases, respectively.

As discussed in the proposed rule, we also analyzed claims data from the September 2021 update of the FY 2021 MedPAR file for cases reporting LITT of other anatomic sites across all MS–DRGs. Although the requestors indicated that LITT is primarily performed on intracranial lesions, as shown in Table 6P.2c associated with the proposed rule, we identified a small number of cases reporting LITT of the lung, rectum, liver, breast, and prostate, for a total of 29 cases where LITT was performed on other body parts/anatomic sites.

For example, we found a total of 5 cases reporting LITT of lung across 5 different MS–DRGs. Of these 5 cases, 2 cases had a longer average length of stay and higher average costs in comparison to all the cases in their respective MS–DRG. Specifically, for MS–DRG 163 (Major Chest Procedures with MCC), we found 1 case reporting LITT of lung with an average length of stay of 17 days and average costs of $41,467. The average length of stay for all cases in MS–DRG 163 is 10.7 days with average costs of $38,367. The data demonstrates a difference of 6.3 days (17 − 10.7 = 6.3) for the average length of stay and a difference of $3,100 in average costs ($41,467 − $38,367 = $3,100) for the 1 case reporting LITT of lung in MS–DRG 163 compared to all the cases in MS–DRG 163. For MS–DRG 167 (Other Respiratory System O.R. Procedures with CC), we found 1 case reporting LITT of lung with an average length of stay of 7 days and average costs of $22,975. The average length of stay for all cases in MS–DRG 167 is 4.6 days with average costs of $15,397. The data demonstrates a difference of 2.4 days (7 − 4.6 = 2.4) for the average length of stay and a difference of $7,578 in average costs ($22,975 − $15,397 = $7,578) for the 1 case reporting LITT of lung in MS–DRG 167 compared to all the cases in MS–DRG 167. The data for the remaining 3 cases reporting LITT of lung demonstrated a shorter average length of stay and lower average costs in comparison to all the cases in their respective MS–DRGs.

We found 1 case reporting LITT of rectum in MS–DRG 357 (Other Digestive System O.R. Procedures with CC) with a shorter average length of stay (4 days versus 5.6 days) and lower average costs ($3,069 versus $18,065) as compared to all the cases in MS–DRG 357. We also found 1 case reporting LITT of liver in MS–DRG 405 (Pancreas Liver and Shunt Procedures with MCC) with a longer average length of stay (20 days versus 12.3 days) and higher average costs ($49,0695 versus $43,771) as compared to all the cases in MS–DRG 405.We also found 1 case reporting LITT of right breast in MS–DRG 580 (Other Skin Subcutaneous Tissue and Breast Procedures with CC) with a longer average length of stay (19 days versus 5.4 days) and higher average costs ($32,064 versus $13,767) as compared to all the cases in MS–DRG 580.

Lastly, we found 21 cases reporting LITT of prostate across 14 MS–DRGs. Of those 21 cases, 6 cases had a longer average length of stay or higher average costs, or both, in comparison to the average length of stay and average costs of all the cases in their respective MS–DRG. For example, in MS–DRG 650 (Kidney Transplant with Hemodialysis with MCC) we found 1 case reporting LITT of prostate with an average length of stay of 36 days and average costs of $67,238. The average length of stay for all cases in MS–DRG 650 is 8.1 days with average costs of $38,139. The data demonstrates a difference of 27.9 days (36 − 8.1 = 27.9) for the average length of stay and a difference of $29,099 in average costs ($67,238 − $38,139 = $29,099) for the 1 case reporting LITT of prostate in MS–

DRG 650 compared to all the cases in MS–DRG 650. We also found 1 case reporting LITT of prostate in MS–DRG 659 (Kidney and Ureter Procedures for Non-Neoplasm with MCC) with an average length of stay of 26 days. The average length of stay for all cases in MS–DRG 659 is 7.8 days, demonstrating a difference of 18.2 days (26 − 7.8 = 18.2). We found 1 case reporting LITT of prostate in MS–DRG 712 (Testes Procedures without CC/MCC) with average costs of $15,669. The average costs for all cases in MS–DRG 712 is $10,482, demonstrating a difference of $5,187 ($15,669 − $10,482 = $5,187). We found 1 case reporting LITT of prostate in MS–DRG 987 with an average length of stay of 23 days and average costs of $35,465. The average length of stay for all cases in MS–DRG 987 is 10.9 days with average costs of $26,657. The data demonstrates a difference of 12.1 days (23 − 10.9 = 12.1) for the average length of stay and a difference of $8,808 in average costs ($35,465 − $26,657 = $8,808) for the 1 case reporting LITT of prostate in MS–DRG 987 compared to all the cases in MS–DRG 987. Lastly, we found 2 cases reporting LITT of prostate in MS–DRG 988 (Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC) with average costs of $17,126. The average costs for all cases in MS–DRG 988 is $13,670, demonstrating a difference of $3,456 ($17,126 − $13,670 = $3,456) for the 2 cases reporting LITT of prostate in MS–DRG 988.

We refer the reader to Table 6P.2c associated with the proposed rule for the detailed findings from our analysis. We note that if the procedure code describing LITT of a specific anatomic site is not listed it is because there were no cases found.

We noted in the proposed rule that for the 10 cases previously described, for which LITT of a different anatomic site from the brain or brain stem was reported and had a longer average length of stay or higher average costs, or both, in comparison to the average length of stay and average costs of all the cases in their respective MS–DRG, that with the exception of MS–DRG 712, all the other MS–DRGs include a ''with MCC'' or ''with CC'' designation, or were reported in a surgical MS–DRG. We stated we believe that these other factors may have contributed to the longer average length of stay and higher average costs for these cases, therefore we conducted additional analyses of the claims data to determine what diagnoses or procedures were also reported. We refer the reader to Table 6P.2d associated with the proposed rule for the findings from our detailed analysis of these 10 cases.

As shown in Table 6P.2d associated with the proposed rule, the data demonstrate that a number of MCC and/or CC secondary diagnoses were reported for each of the 10 cases and that the surgical procedures that were reported in addition to the LITT procedure seem to have contributed to the longer average length of stay and higher average costs for those cases when compared to the average length of stay and average costs for all the cases in their respective MS–DRG. For example, in case number 1 there are 2 diagnoses that are designated as MCC conditions and 5 diagnoses that that are designated as CC conditions with procedure codes describing a kidney transplant, hemodialysis, and insertion of a ureteral stent that were reported along with LITT of prostate. For case number 3 there are 4 diagnoses that are designated as MCC conditions and 6 diagnoses that are designated as CC conditions with procedure codes describing bronchoscopic treatment of a bronchial tumor with and without stents, as well as the use of mechanical ventilation. Overall, the data appear to indicate that the performance of the LITT procedure was not the underlying reason for, or main driver of, the increase in resource utilization for those cases.

As noted in the proposed rule, the requestors indicated that LITT is primarily being performed on intracranial lesions. However, as previously summarized, we identified a limited number of cases reporting LITT procedures for other anatomic sites. We stated in the proposed rule that we are interested in comments regarding the use of and experience with LITT for these other anatomic sites.

As discussed in the proposed rule, based on our analysis of the FY 2021 MedPAR claims data for cases reporting LITT of brain or brain stem (codes D0Y0KZZ and D0Y1KZZ) in MS–DRGs 040, 041, and 042, we agree with the requestors that the average costs of these cases are higher as compared to the average costs of all cases assigned to MS–DRGs 040, 041, and 042. For the reasons summarized, in the proposed rule we also stated we believe that other factors, including the reporting of secondary MCC and CC diagnoses, may be contributing to the higher average costs for these cases. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44813), we examined procedure codes D0Y0KZZ and D0Y1KZZ describing LITT of brain and brain stem, respectively, and stated that the technique to perform the LITT procedure on these structures is considered minimally invasive and does not involve a craniotomy, therefore, continued assignment to the craniotomy MS–DRGs is not clinically appropriate. As noted in the proposed rule, our clinical advisors continue to maintain that LITT is a minimally invasive procedure, requiring only a tiny incision for purposes of a burr hole and that patients are often only kept overnight (as reflected in the detailed claims data). However, we stated that we also recognize that craniotomy and LITT share common procedural characteristics including use of an operating room, carry risk of immediate intracranial bleeding or infection, and cause tissue to be immediately destroyed or excised. We noted that while the data do not demonstrate that the LITT procedure is the underlying reason for the higher average costs and consumption of resources for the small number of cases reporting LITT of brain (54 cases) or brain stem (2 cases) that we found in MS–DRGs 040, 041, and 042, the data do demonstrate that the patients receiving this treatment therapy have brain tumors or epilepsy combined with multiple comorbidities or chronic conditions necessitating long-term use of medications, or both, and we noted the indications for LITT (brain tumors and epileptic foci) are better aligned with MS–DRGs 025, 026, and 027 as compared to MS–DRGs 040, 041, and 042.

As discussed in the proposed rule, we intend to more fully evaluate the logic for the procedures specifically involving a craniotomy, as well as the overall structure of MS–DRGs 023 through 027, and we believe that reassignment of cases reporting LITT of brain or brain stem to MS–DRGs 025, 026, and 027 would be an appropriate first step in connection with these efforts. For example, while we recognize the distinctions between open craniotomy procedures and minimally invasive percutaneous intracranial procedures, we also recognize that the current logic for MS–DRGs 025 through 027 also includes other endovascular intracranial procedures performed using percutaneous or percutaneous endoscopic approaches, and we believe that further review of the clinical coherence of the procedures assigned to these MS–DRGs may be warranted. Our clinical advisors noted that while the typical patient treated with LITT usually has a single small scalp incision through which a hole approximately the diameter of a straw is drilled, with no extensive surgical exposure, that LITT

can still be employed for another subset of more complex patients, including patients with primary brain malignancies and those with larger metastatic lesions or multiple lesions. For this subset of more complex patients, a longer post-operative stay with direct medical supervision may be necessary. As such, we stated in the proposed rule that we believe reassigning these procedures to MS–DRGs 025 through 027 for FY 2023 would be appropriate as we consider restructuring MS–DRGs 023 through 027, including how to better align the clinical indications with the performance of specific intracranial procedures. Accordingly, for these reasons, we stated in the proposed rule that in the event there is not support for the proposed reclassification of LITT procedures and the corresponding new procedure codes as presented at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting, we were proposing to reassign the existing procedure codes describing LITT of the brain or brain stem from MS–DRGs 040, 041, and 042 to MS–DRGs 025, 026, and 027 for FY 2023. We also proposed to maintain the MS–DRG assignments for the existing procedure codes describing LITT of other anatomic sites as finalized and displayed in Table 6P.2b in association with the FY 2022 IPPS/LTCH PPS final rule, for FY 2023. Lastly, we noted in the proposed rule that we did not receive any comments or requests to reconsider those finalized MS–DRG assignments for FY 2023.

As noted, we stated in the proposed rule that we were proposing to reassign the existing procedure codes describing LITT of the brain or brain stem from MS–DRGs 040, 041, and 042 to MS–DRGs 025, 026, and 027 for FY 2023, in the event there was not support for the proposed reclassification of LITT procedures and the corresponding new procedure codes as presented at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting. As the proposed reclassification of the LITT procedures and the corresponding new procedure codes were approved following the March meeting, and the existing procedure codes D0Y0KZZ (Laser interstitial thermal therapy of brain) and D0Y1KZZ (Laser interstitial thermal therapy of brain stem) will be deleted effective October 1, 2022, we are not finalizing the proposed reassignment of these existing codes for FY 2023. As previously noted, and as reflected in Table 6B.—New Procedure Codes associated with this final rule, the new procedure codes describing LITT of brain (root operation Destruction) are assigned to MS–DRGs 025, 026 and 027 for FY 2023. We did not receive any public comments on our proposal to maintain the MS–DRG assignments for the existing procedure codes describing LITT of other anatomic sites as finalized and displayed in Table 6P.2b in association with the FY 2022 IPPS/LTCH PPS final rule, for FY 2023. As previously noted, the existing procedure codes describing LITT of other anatomic sites will also be deleted effective October 1, 2023; therefore, we are not finalizing the proposed reassignment of these existing codes for FY 2023. The MS–DRG assignments for the newly approved procedure codes describing LITT of other anatomic sites for FY 2023 are displayed in Table 6B in association with this final rule.

As noted in the proposed rule, in connection with our analysis of cases reporting LITT procedures performed on the brain or brain stem in MDC 01, we have started to examine the logic for case assignment to MS–DRGs 023 through 027 to determine where further refinements could potentially be made to better account for differences in the technical complexity and resource utilization among the procedures that are currently assigned to those MS–DRGs. Specifically, we are in the process of evaluating procedures that are performed using an open craniotomy (where it is necessary to surgically remove a portion of the skull) versus a percutaneous burr hole (where a hole approximately the size of a pencil is drilled) to obtain access to the brain in the performance of a procedure. We are also reviewing the indications for these procedures, for example, malignant neoplasms versus epilepsy to consider if there may be merit in considering restructuring the current MS–DRGs to better recognize the clinical distinctions of these patient populations in the MS–DRGs. We believe it is worthwhile to also compare the claims data for epilepsy patients who are treated with a neurostimulator implant versus a LITT procedure, as well as the claims data for patients with a diagnosis of epilepsy or malignant neoplasms who undergo a LITT procedure. Our analysis also includes reviewing the claims data with regard to the cases that reflect a procedure that is generally performed with another O.R. procedure versus a standalone procedure.

As we continue this analysis of the claims data with respect to MS–DRGs 023 through 027, we stated that we are also seeking public comments and feedback on other factors that should be considered in the potential restructuring of these MS–DRGs.

Comment: In response to CMS's request for public comment and feedback on the potential restructuring of the craniotomy MS–DRGs for future consideration, some commenters disagreed and stated that such a restructuring is not necessary. These commenters stated that should CMS consider future modifications to the logic for case assignment to MS–DRGs 023 through 027, the agency provide adequate notice for interested parties to assess the impact of any proposed changes.

Another commenter expressed appreciation that CMS indicated it is continuing to analyze if additional restructuring for MS–DRGs 023 through 027 may be warranted and agreed that the logic for these MS–DRGs has become more complex. The commenter stated they will be performing analyses and plan to submit their findings by the October 20, 2022 deadline. Another commenter urged CMS to also consider the costs of procedures with respect to whether a device is inserted or implanted in combination with the approach and clinical indications because of the various diagnoses and procedures that may group to MS–DRGs 023 through 027. This commenter expressed support for further collaboration to better align resources and clinical characteristics among within these MS–DRGs.

Another commenter who also expressed appreciation that CMS has signaled its intent on analyzing MS–DRGs 023 through 027 recommended that CMS also expand its analysis to include MS–DRGs 020 through 022 (Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage with MCC, with CC, and without CC/MCC, respectively). According to the commenter, the payment rates for a subset of the procedures that group to these MS–DRGs appear to no longer adequately reflect the utilization of resources. The commenter encouraged CMS to analyze these MS–DRGs and determine if additional modifications may be warranted.

Response: We thank the commenters for their feedback and will take these recommendations into consideration as we further examine the logic for case assignment. We note that we would address any proposed modifications to the existing logic in future rulemaking.

As previously described in the proposed rule and this final rule, we are examining procedures by their approach (open versus percutaneous), clinical indications, and procedures that involve the insertion or implantation of a device. We recognize the logic for MS–DRGs 023 through 027 has grown more

complex over the years and believe there is opportunity for further refinement. We refer the reader to the ICD–10 MS–DRG Definitions Manual, version 40, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 023 through 027. Feedback and other suggestions may be submitted by October 20, 2022 and directed to the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™), discussed in section II.D.1.b of the preamble of this final rule at: *https://mearis.cms.gov/public/home*.

b. Vagus Nerve Stimulation

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28141 through 28151), we discussed a request we received to review the MS–DRG assignment for cases that identify patients who receive an implantable vagus nerve stimulation system for heart failure. The vagus nerve, also called the X cranial nerve or the 10th cranial nerve, is the longest and most complex of the cranial nerves. There is one vagus nerve on each side of the body that runs from the brain through the face and thorax to the abdomen. According to the requestor, cranial nerve stimulation (CNS), which includes vagus nerve stimulation, is a well-established therapy for various indications including epilepsy, treatment resistant depression (TRD) and obstructive sleep apnea (OSA), and is now being investigated and studied for use in patients with heart failure.

According to the requestor, heart failure, or the heart's inability to pump an adequate supply of blood and oxygen to support the other organs of the body, is an autonomic nervous system dysfunction. The brain controls the function of the heart through the sympathetic branch and the parasympathetic branches of the autonomic nervous system. In heart failure, there is an imbalance in the autonomic nervous system. The vagus nerve stimulation system for heart failure is comprised of an implantable pulse generator, an electrical lead, and a programming computer system. The pulse generator, which is usually implanted just under the skin of the pectoral region, sends the energy to the vagus nerve through the lead. The lead is a flexible insulated wire that is guided under the skin from the chest up to the neck and is implanted onto the vagus nerve and transmits tiny electrical impulses from the generator to the nerve. These electrical impulses to the vagus nerve are intended to activate the parasympathetic branch of the autonomic nervous system to restore balance.

The requestor stated that cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis code describing epilepsy, TRD or OSA are assigned to surgical MS–DRGs 040, 041 and 042 (Peripheral Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator, and without CC/MCC, respectively) in MDC 01 (Diseases and Disorders of the Nervous System). However, when the same codes describing the insertion of a neurostimulator lead onto the vagus nerve and the insertion of a stimulator generator are reported with a principal diagnosis of heart failure, the cases instead are assigned to surgical MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC, without MCC respectively) in MDC 05 (Diseases and Disorders of the Circulatory System).

The requestor stated that the treatment of autonomic nervous system dysfunction is the underlying therapeutic objective of cranial nerve stimulation for heart failure, and therefore the diagnosis of heart failure is more clinically coherent with other diagnoses in MDC 01. As a result, the requestor, who is developing the VITARIA® System, an active implantable neuromodulation system that uses vagus nerve stimulation to deliver autonomic regulation therapy (ART) for an indicated use that includes patients who have moderate to severe heart failure, submitted a request to reassign cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis code describing heart failure, from MS–DRGs 252, 253 and 254 in MDC 05 to MS–DRGs 040, 041 and 042 in MDC 01. This requestor also submitted an application for new technology add-on payment for FY 2023. As discussed in section II.F.7. of the preamble of this final rule, the new technology add-on payment application for the VITARIA® System for FY 2023 was withdrawn prior to the issuance of this final rule.

According to the requestor, the following ICD–10–PCS procedure code pair identifies the insertion of a vagus nerve stimulation system for heart failure:

ICD-10-PCS Code	Description
00HE0MZ with 0JH60BZ	Insertion of neurostimulator lead into cranial nerve, open approach
	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach

We stated in the FY 2023 IPPS/LTCH PPS proposed rule that the requestor performed its own analysis of Medicare claims from 2020 and stated that it found that patients enrolled in their pivotal clinical trials had an average length of stay of 6.38 days. According to the requestor this finding indicated a resource coherence more similar to cases assigned to MS–DRGs 040, 041 and 042, whose average lengths of stay ranges from 2 to 8 days, when compared to the average lengths of stay of 1 to 3 days for cases assigned to MS–DRGs 252 and 253. The requestor stated their own analysis of 2019 and 2020 Medicare claims data also showed that fewer than 11 cases with procedure codes describing the implantation of a vagus nerve stimulation system map to MS–DRGs 252, 253 and 254 annually but it is expected that Medicare patients will receive vagus nerve stimulation system for heart failure on an inpatient basis. Because of the shared clinical and resource similarity of the procedure to implant the VITARIA® system to other CNS procedures, regardless of indication, the requestor stated that CNS procedures for the treatment of heart failure should also be assigned to MS–DRGs 040, 041 and 042. The requestor also noted that the title of MS–DRGs

252, 253 and 254 is ''Other Vascular Procedures with MCC, with CC, without MCC respectively''. Since no vascular access is involved in the procedure to implant vagus nerve stimulation systems, the requestor stated MS–DRGs 252, 253 and 254 were not appropriate mappings for these procedures.

We stated in the proposed rule that the ICD–10–CM diagnosis codes that describe heart failure are found in the following table. These diagnosis codes are all currently assigned to MDC 05.

BILLING CODE 4120–01–P

ICD-10-CM Code	Description
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery

The ICD–10–PCS codes that identify the insertion of a neurostimulator lead onto the vagus nerve are listed in the following table.

ICD-10-PCS Code	Description
00HE0MZ	Insertion of neurostimulator lead into cranial nerve, open approach
00HE3MZ	Insertion of neurostimulator lead into cranial nerve, percutaneous approach
00HE4MZ	Insertion of neurostimulator lead into cranial nerve, percutaneous endoscopic approach

The ICD–10–PCS codes that identify the insertion of a stimulator generator are listed in the following table.

ICD-10-PCS Code	Description
0JH60BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH63BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH70BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70MZ	Insertion of stimulator generator into back subcutaneous tissue and fascia, open approach
0JH73BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73MZ	Insertion of stimulator generator into back subcutaneous tissue and fascia, percutaneous approach

ICD-10-PCS Code	Description
0JH80BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80MZ	Insertion of stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH83BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83MZ	Insertion of stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH60BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH63BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63MZ	Insertion of stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH70BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach

ICD-10-PCS Code	Description
0JH70DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70MZ	Insertion of stimulator generator into back subcutaneous tissue and fascia, open approach
0JH73BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73MZ	Insertion of stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH80BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80MZ	Insertion of stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH83BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83MZ	Insertion of stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach

We stated our analysis of this grouping issue confirmed that, when a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator are reported with a principal diagnosis code describing heart failure, these cases group to surgical MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC, without MCC respectively).

We noted that cases involving the use of a peripheral neurostimulator and a diagnosis from MDC 01 are assigned to MS–DRG 041 only. The GROUPER logic for MS–DRGs 040, 041, and 042 is reflected in the logic table:

MCC	CC	Peripheral Neurostimulator Combinations	MS-DRG
Yes	n/a	n/a	040 (Peripheral Cranial Nerve and Other Nervous System Procedures with MCC)
No	Yes	n/a	041 (Peripheral Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator)
No	No	Yes	041 (Peripheral Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator)
No	No	No	042 (Peripheral Cranial Nerve and Other Nervous System Procedures without CC/MCC)

We refer the reader to the ICD–10 MS–DRG Version 39.1 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) for complete documentation of the GROUPER logic for the listed MS–DRGs.

In the proposed rule, we stated that we examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 252, 253 and 254 to identify the subset of cases within MS–DRGs 252, 253 and 254 reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis of heart failure. We stated we found zero cases in MS–DRGs 252, 253 and 254 reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis of heart failure. In an attempt to further examine this issue, we then examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 252, 253 and 254 to identify the subset of cases within MS–DRGs 252, 253 and 254 reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a secondary diagnosis of heart failure and similarly found zero cases.

We indicated in the proposed rule that the results of the claims analysis demonstrated that there was not sufficient claims data in the MedPAR file on which to assess the resource use of cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal or secondary diagnosis of heart failure as compared to other cases assigned to MS–DRGs 252, 253, and 254.

As discussed in the proposed rule, in reviewing the requestor's concerns regarding clinical coherence, our clinical advisors acknowledged that heart failure is a complex syndrome involving autonomic nervous system dysfunction, however our clinical advisors disagreed with assigning the diagnosis codes describing heart failure to MDC 01 (Diseases and Disorders of the Nervous System). Our clinical advisors noted the concept of clinical coherence requires that the patient characteristics included in the definition of each MS–DRG relate to a common organ system or etiology. As the listed diagnosis codes describe heart failure, we stated these diagnosis codes are appropriately assigned to MDC 05 (Diseases and Disorders of the Circulatory System). Our clinical advisors also stated it would not be appropriate to move these diagnoses into MDC 01 because it could inadvertently cause cases reporting these same MDC 05 diagnoses with a circulatory system procedure to be assigned to an unrelated MS–DRG because whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in a MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

To further examine the impact of moving the diagnoses describing heart failure into MDC 01, we stated we analyzed claims data for cases reporting a circulatory system O.R. procedure and a principal diagnosis of heart failure. Our findings are reflected in the following table.

Cases Reporting Circulatory System O.R. Procedures with a Principal Diagnosis of Heart Failure				
MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
215	Other Heart Assist System Implant	375	12.9	$89,802
216	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC	554	17.7	$90,282
217	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC	9	9.2	$59,655
218	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC	2	6	$36,309
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	147	16.8	$85,238
220	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC	7	8.4	$62,843
222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI HF or Shock with MCC	923	11.6	$61,254
223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI HF or Shock without MCC	80	6.3	$40,806
224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI HF or Shock with MCC	1	6	$41,102
226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC	1,602	8.1	$51,116
227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC	219	3.5	$40,176
228	Other Cardiothoracic Procedures with MCC	345	11.4	$43,864
229	Other Cardiothoracic Procedures without MCC	9	5.6	$28,662
231	Coronary Bypass with PTCA with MCC	13	17.2	$91,948
233	Coronary Bypass with Cardiac Catheterization or Open Ablation with MCC	482	17.3	$75,283
234	Coronary Bypass with Cardiac Catheterization or Open Ablation without MCC	4	19.8	$77,000
235	Coronary Bypass without Cardiac Catheterization with MCC	70	15	$61,655
236	Coronary Bypass without Cardiac Catheterization without MCC	6	5	$41,809
239	Amputation for Circulatory System Disorders Except Upper Limb and Toe with MCC	196	17.6	$43,110
240	Amputation for Circulatory System Disorders Except Upper Limb and Toe with CC	2	5	$10,803
242	Permanent Cardiac Pacemaker Implant with MCC	1,993	8.7	$33,121
243	Permanent Cardiac Pacemaker Implant with CC	105	5.2	$23,927
244	Permanent Cardiac Pacemaker Implant without CC/MCC	5	3.4	$21,763

Cases Reporting Circulatory System O.R. Procedures with a Principal Diagnosis of Heart Failure				
MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
245	AICD Generator Procedures	196	7.6	$42,062
246	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents	4,529	7.4	$27,962
247	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC	174	4.7	$19,268
248	Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents	92	7.3	$26,922
249	Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC	7	5.1	$19,763
250	Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC	288	7	$25,284
251	Percutaneous Cardiovascular Procedures without Coronary Artery Stent without MCC	8	3.4	$14,789
252	Other Vascular Procedures with MCC	1,603	10.4	$32,014
253	Other Vascular Procedures with CC	29	4.6	$21,692
254	Other Vascular Procedures without CC/MCC	2	1	$10,169
255	Upper Limb and Toe Amputation for Circulatory System Disorders with MCC	105	10.7	$24,075
256	Upper Limb and Toe Amputation for Circulatory System Disorders with CC	2	8	$14,155
258	Cardiac Pacemaker Device Replacement with MCC	267	6.8	$22,749
259	Cardiac Pacemaker Device Replacement without MCC	28	4.3	$21,145
260	Cardiac Pacemaker Revision Except Device Replacement with MCC	279	8.4	$28,176
261	Cardiac Pacemaker Revision Except Device Replacement with CC	20	4.3	$17,726
262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC	3	2.7	$18,186
263	Vein Ligation and Stripping	9	35.7	$50,529
264	Other Circulatory System O.R. Procedures	2,422	10.7	$28,866
265	AICD Lead Procedures	83	10	$38,286
266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC	666	13.9	$76,663
267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC	36	3.8	$44,643
268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC	46	16.7	$62,285
269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC	1	1	$14,357
270	Other Major Cardiovascular Procedures with MCC	1,026	13.8	$48,958
271	Other Major Cardiovascular Procedures with CC	22	8.7	$26,730
272	Other Major Cardiovascular Procedures without CC/MCC	2	1.5	$8,289
273	Percutaneous and Other Intracardiac Procedures with MCC	1,064	8.8	$33,132
274	Percutaneous and Other Intracardiac Procedures without MCC	41	6.2	$26,180
	Total Cases	**20,199**	**9.9**	**$40,428**

As shown in the table, if we were to move diagnosis codes describing heart failure to MDC 01, 20,199 cases would be assigned to the surgical class referred to as ''unrelated operating room procedures'' as an unintended consequence because the surgical procedure reported on the claim would be considered unrelated to the MDC to which the case was assigned based on the principal diagnosis.

In response to the requestor's concerns regarding the title of MS–DRGs 252, 253 and 254, we noted that, as stated in the ICD–10 MS–DRG Definitions Manual, ''In each MDC there is usually a medical and a surgical class referred to as ''other medical diseases'' and ''other surgical procedures,'' respectively. The ''other'' medical and surgical classes are not as precisely defined from a clinical perspective. The other classes would include diagnoses or procedures which were infrequently encountered or not well defined clinically. For example, the ''other'' medical class for the Respiratory System MDC would contain the diagnoses ''other somatoform disorders'' and ''congenital malformation of the respiratory system,'' while the ''other'' surgical class for the female reproductive MDC would contain the surgical procedures ''excision of liver'' (liver biopsy in ICD–9–CM) and ''inspection of peritoneal cavity'' (exploratory laparotomy in ICD–9–CM). The ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC. There are, however, also patients who receive surgical procedures which are completely unrelated to the MDC to which the patient was assigned. An example of such a patient would be a patient with a principal diagnosis of pneumonia whose only surgical procedure is a destruction of prostate (transurethral prostatectomy in ICD–9–CM). Such patients are assigned to a surgical class referred to as ''unrelated operating room procedures.'' '' We further noted that MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) are examples of the ''other'' surgical class, therefore it is expected that there will be procedures not as precisely clinically aligned within the definition (logic) of these MS–DRGs.

We stated in the proposed rule that considering that there was no data in the FY 2021 MedPAR file to support a reassignment of these cases based on resource consumption, the analysis of clinical coherence as discussed previously, and the impact that moving the diagnoses describing heart failure into MDC 01 from MDC 05 would have on heart failure cases, we did not believe a reassignment of these cases was appropriate at this time. We stated we could continue to evaluate the clinical coherence and resource consumption costs that impact this subset of cases and their current MS–DRG assignment as data become available for future rulemaking.

In summary for the reasons stated previously, we did not propose to reassign cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis of heart failure from MS–DRGs 252, 253 and 254 to MS–DRGs 040, 041 and 042.

Comment: Commenters expressed support for CMS' decision to not propose to reassign cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis of heart failure from MS–DRGs 252, 253 and 254 to MS–DRGs 040, 041 and 042.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current assignment of cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis of heart failure to MS–DRGs 252, 253 and 254, without modification, for FY 2023.

We further stated in the proposed rule that as we examined the GROUPER logic that would determine an assignment of a case to MS–DRGs 252, 253 and 254, we noted the logic for MS–DRGs 252, 253 and 254 includes ICD–10–PCS procedure codes that describe the insertion of the stimulator generator. We refer the reader to the ICD–10 MS–DRG Version 39.1 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) for complete documentation of the GROUPER logic for the listed MS–DRGs. We stated that during our review of the stimulator generator insertion procedures assigned to these MS–DRGs, we identified the following 24 procedure codes that describe the insertion of a stimulator generator, differentiated by device type (for example single array or multiple array), that did not exist in the logic for MS–DRGs 252, 253 and 254.

ICD-10-PCS Code	Description
0JH60BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH60EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach
0JH63BZ	Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63CZ	Insertion of single array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63DZ	Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH63EZ	Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, percutaneous approach
0JH70BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, open approach
0JH70EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, open approach
0JH73BZ	Insertion of single array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73CZ	Insertion of single array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73DZ	Insertion of multiple array stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH73EZ	Insertion of multiple array rechargeable stimulator generator into back subcutaneous tissue and fascia, percutaneous approach
0JH80BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH80EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, open approach
0JH83BZ	Insertion of single array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83CZ	Insertion of single array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83DZ	Insertion of multiple array stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach
0JH83EZ	Insertion of multiple array rechargeable stimulator generator into abdomen subcutaneous tissue and fascia, percutaneous approach

For clinical consistency with the other procedure codes describing the insertion of the stimulator generator currently assigned to these MS–DRGs, we proposed to add the 24 ICD–10–PCS codes listed previously to MS–DRGs 252, 253 and 254, (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System) effective October 1, 2022 for FY 2023.

Comment: Commenters supported the proposal to add the 24 ICD–10–PCS codes to MS–DRGs 252, 253 and 254, (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System).

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the 24 ICD–10–PCS codes listed previously to MS–DRGs 252, 253 and 254, (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System) without modification, effective October 1, 2022 for FY 2023.

Also, in the proposed rule we stated that as we examined the GROUPER logic that would determine an assignment of a case to MS–DRG 041,

we noted that the logic for case assignment to MS–DRG 041 as displayed in the ICD–10 MS–DRG Version 39.1 Definitions Manual, available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* contains code combinations or ''clusters'' representing the insertion of a neurostimulator lead and the insertion of a stimulator generator that are captured under a list referred to as ''Peripheral Neurostimulators.'' During our review of the procedure code clusters in this list, we noted that ICD–10–PCS procedure code clusters describing the insertion of a neurostimulator lead and the insertion of the stimulator generator differentiated by device type (for example single array or multiple array), approach and anatomical site placement are captured. However, procedure code clusters describing the insertion of stimulator generator, that is not differentiated by device type, and a neurostimulator lead were inadvertently excluded. We refer the reader to Table 6P.3a associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for the list of the 108 ICD–10–PCS code clusters that were inadvertently excluded and do not exist in the logic for MS–DRG 041.

For clinical consistency, our clinical advisors supported the addition of the 108 procedure code clusters to the GROUPER logic list referred to as ''Peripheral Neurostimulators'' for MS–DRG 041 that describe the insertion of stimulator generator, not differentiated by device type, and a neurostimulator lead. Therefore, we proposed to add the 108 ICD–10–PCS code clusters listed in Table 6P.3a in association with the proposed rule that describe the insertion of a stimulator generator, that is not differentiated by device type, and a neurostimulator lead to MS–DRG 041, effective October 1, 2022 for FY 2023.

Comment: Commenters expressed support for CMS' proposal to add the 108 ICD–10–PCS code clusters listed in Table 6P.3a in association with the proposed rule that describe the insertion of a stimulator generator, that is not differentiated by device type, and a neurostimulator lead to MS–DRG 041. A commenter stated that this proposal will clinically align these procedures with other procedures in their respective MS–DRGs.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the 108 procedure code clusters listed in Table 6P.3a in association with the proposed rule that describe the insertion of stimulator generator, not differentiated by device type, and a neurostimulator lead to the GROUPER logic list referred to as ''Peripheral Neurostimulators'' for MS–DRG 041 (Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator) without modification, effective October 1, 2022 for FY 2023.

4. MDC 02 (Diseases and Disorders of the Eye): Retinal Artery Occlusion

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28151 through 28155), we discussed a request we received to reassign cases reporting diagnosis codes describing central retinal artery occlusion, and the closely allied condition branch retinal artery occlusion, from MS–DRG 123 (Neurological Eye Disorders) in MDC 02 (Diseases and Disorders of the Eye) to MS–DRGs 061, 062, and 063 (Ischemic Stroke Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC, and without CC/MCC, respectively) in MDC 01 (Diseases and Disorders of the Nervous System).

Retinal artery occlusion refers to blockage of the retinal artery that carries oxygen to the nerve cells in the retina at the back of the eye, often by an embolus or thrombus. A blockage in the main artery in the retina is called central retinal artery occlusion (CRAO). A blockage in a smaller artery is called branch retinal artery occlusion (BRAO). According to the requestor, in the current mapping to MS–DRG 123, diagnoses of CRAO and BRAO are being captured inappropriately as eye disorders in MDC 02. Instead, the requestor stated that CRAO and BRAO are forms of acute ischemic stroke which occur when a vessel supplying blood to the brain is obstructed.

The requestor stated the retina is a core component of the central nervous system and there is growing recognition that damage to it is a vascular neurological problem and not an ophthalmological one. Patients with CRAO or BRAO are typically very sick, have an underlying condition, and are at imminent risk for further events including heart attack or brain stroke. A diagnosis of CRAO or BRAO requires an urgent, structured and multidisciplinary team-based examination to evaluate and treat other diagnoses that may be present such as high blood pressure, dyslipidemia, diabetes mellitus, obesity, obstructive sleep apnea and smoking to ameliorate the risks of a subsequent, potentially lethal, cardiovascular event.

The requestor further stated new evidence outlines treatment of patients with CRAO with acute stroke protocols, specifically with intravenous thrombolysis (IV tPA) or hyperbaric oxygen therapy (HBOT), to improve outcomes. According to the requestor, BRAO is less commonly treated with IV tPA than CRAO but also requires an urgent and thorough diagnostic workup as with any other form of stroke. The requestor stated the current assignment of these conditions to MS–DRG 123 does not properly recognize disease complexity and allocation of resources for care for these cases. The requestor stated that patients with CRAO or BRAO more closely resemble patients currently mapped to MS–DRGs 061, 062, and 063 in terms of in resource intensity and criticality and that in instances where HBOT is the chosen treatment modality, any revised MS–DRG mapping should include the ICD–10–PCS codes for HBOT.

As noted in the proposed rule, the ICD–10–CM codes that describe CRAO and BRAO are found in the following table.

ICD-10-CM Code	Description
H34.10	Central retinal artery occlusion, unspecified eye
H34.11	Central retinal artery occlusion, right eye
H34.12	Central retinal artery occlusion, left eye
H34.13	Central retinal artery occlusion, bilateral
H34.231	Retinal artery branch occlusion, right eye
H34.232	Retinal artery branch occlusion, left eye
H34.233	Retinal artery branch occlusion, bilateral
H34.239	Retinal artery branch occlusion, unspecified eye

Thrombolytic therapy is identified with the following ICD–10–PCS procedure codes.

ICD-10-PCS Code	Description
3E03017	Introduction of other thrombolytic into peripheral vein, open approach
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach
3E04017	Introduction of other thrombolytic into central vein, open approach
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach
3E05017	Introduction of other thrombolytic into peripheral artery, open approach
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach
3E06017	Introduction of other thrombolytic into central artery, open approach
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach

The requestor identified three ICD–10–PCS codes that they stated describe HBOT.

ICD-10-PCS Code	Description
5A05121	Extracorporeal hyperbaric oxygenation, intermittent
6A150ZZ	Decompression, circulatory, single
6A151ZZ	Decompression, circulatory, multiple

We stated in the proposed rule that during our review of this issue, we included the three procedure codes as identified by the requestor as describing HBOT, as well as the similar procedure code 5A05221 (Extracorporeal hyperbaric oxygenation, continuous) that also describes HBOT, differing only in duration.

We stated that our analysis of this grouping issue confirmed that, when a procedure code describing the administration of a thrombolytic agent or a procedure code describing HBOT is reported with principal diagnosis code describing CRAO or BRAO, these cases group to medical MS–DRG 123. We began our analysis by examining claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRG 123 to (1) identify cases reporting a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent or a procedure code describing HBOT; (2) identify cases reporting diagnosis codes describing CRAO or BRAO with a procedure code describing HBOT; and (3) identify cases reporting diagnosis codes describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
123	All cases	2,642	2.5	$6,457
	Cases reporting a principal diagnosis of CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent or a procedure code describing HBOT	774	2.2	$5,482
	Cases reporting a procedure code describing HBOT with a principal diagnosis of CRAO or BRAO	9	2	$6,491
	Cases reporting a procedure code describing the administration of a thrombolytic agent with a principal diagnosis of CRAO or BRAO	47	2.3	$14,335
	All other cases	1,812	2.6	$6,669

As shown in the table, we identified a total of 2,642 cases within MS–DRG 123 with an average length of stay of 2.5 days and average costs of $6,457. Of these 2,642 cases, there are 774 cases that reported a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent or a procedure code describing HBOT with an average length of stay of 2.2 days and average costs of $5,482. There are nine cases that reported a principal diagnosis code describing CRAO or BRAO with a procedure code describing HBOT with an average length of stay of 2 days and average costs of $6,491. There are 47 cases that reported a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent with an average length of stay of 2.3 days and average costs of $14,335.

The data analysis shows that the 774 cases in MS–DRG 123 reporting a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent or a procedure code describing HBOT have average costs lower than the average costs in the FY 2021 MedPAR file for MS–DRG 123 ($5,482 compared to $6,457), and the average length of stay is shorter (2.2 days compared to 2.5 days). For the nine cases in MS–DRG 123 reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing HBOT, the average length of stay is shorter (2 days compared to 2.5 days) and the average costs ($6,491 compared to $6,457) are slightly higher than the average length of stay and average costs compared to all cases in that MS–DRG. For the 47 cases in MS–DRG 123 reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent, the average length of stay is slightly shorter (2.3 days compared to 2.5 days) and the average costs are higher ($14,335 compared to $6,457) than the average length of stay and average costs compared to all cases in that MS–DRG.

We also examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 061, 062, and 063. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
061	4,531	6.6	$23,720
062	7,955	3.7	$15,733
063	1,548	2.5	$13,023

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We stated in the proposed rule that because MS–DRG 123 is a base DRG and there is a three-way split within MS–DRGs 061, 062, and 063, we also analyzed the 47 cases reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent and the nine cases reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing HBOT for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
123	Cases reporting procedures describing the administration of a thrombolytic agent with a principal diagnosis of CRAO or BRAO with MCC	9	3.2	$20,220
	Cases reporting a procedure code describing HBOT with a principal diagnosis of CRAO or BRAO with MCC	1	3	$10,768
	Cases reporting procedures describing the administration of a thrombolytic agent with a principal diagnosis of CRAO or BRAO with CC	19	2.3	$13,145
	Cases reporting a procedure code describing HBOT with a principal diagnosis of CRAO or BRAO with CC	3	2	$6,107
	Cases reporting procedures describing the administration of a thrombolytic agent with a principal diagnosis of CRAO or BRAO without CC/MCC	19	1.8	$12,737
	Cases reporting a procedure code describing HBOT with a principal diagnosis of CRAO or BRAO without CC/MCC	5	1.8	$5,867

We stated that this data analysis showed that the cases in MS–DRG 123 reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or with a procedure code describing HBOT when distributed based on the presence or absence of a secondary diagnosis designated as a CC or an MCC have average costs lower than the average costs in the FY 2021 MedPAR file for MS–DRGs 061, 062, and 063 respectively, and the average lengths of stay are shorter. Accordingly, we stated that we did not believe the data adequately supported a potential reassignment of these cases to MS–DRGs 061, 062, and 063 respectively.

Our clinical advisors reviewed this issue and the related data analysis and did not believe that the small subset of patients with a diagnosis of CRAO or BRAO receiving a thrombolytic agent or hyperbaric oxygen therapy warranted a separate MS–DRG or reassignment at this time. We stated our clinical advisors noted the average costs for cases of patients with a diagnosis of CRAO or BRAO receiving HBOT are only slightly higher than the average costs for all cases in MS–DRG 123 ($6,491 compared to $6,457). The average costs for cases of patients with a diagnosis of CRAO or BRAO receiving a thrombolytic agent are higher than the average costs for all cases in MS–DRG 123 however when distributed based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC), we stated that it was unclear to what degree the higher average costs for these cases are attributable to the severity of illness of the patient and other circumstances of the admission as opposed to the administration of a thrombolytic agent, as the claims data reflects a wide variance with regard to average costs for these cases.

Our clinical advisors further noted that ischemia is defined as a condition in which the blood vessels become blocked, and blood flow is stopped or reduced. The condition has many potential causes, including a blockage caused by a blood clot, or due to buildup of deposits, such as cholesterol. Ischemia can occur anywhere in the body, and the different names for the condition depend on the organ or body part affected such as the brain (cerebral ischemia), heart (ischemic heart disease, myocardial ischemia, or cardiac ischemia), and intestines (mesenteric ischemia or bowel ischemia), legs (critical limb ischemia—a form of peripheral artery disease), and skin (cutaneous ischemia), while they are similar in that they all involve a blocked blood vessel.

In ICD–10 the body or organ system is the axis of the classification and diagnosis codes describing ischemia affecting other body parts are classified by the body or organ system affected. For example, codes describing myocardial ischemia are assigned to MDC 05 (Diseases and Disorders of the Circulatory System) and codes describing mesenteric ischemia are assigned to MDC 06 (Diseases and Disorders of the Digestive System). Our clinical advisors disagreed with assigning the diagnosis codes describing CRAO and BRAO to MDC 01. Our clinical advisors noted the concept of clinical coherence generally requires that the patient characteristics included in the definition of each MS–DRG relate to a common organ system or etiology and that a specific medical specialty should typically provide care to the patients in the DRG. While closely related, the eyes and the brain are different organs. Our clinical advisors stated that because the diagnosis codes used to report CRAO and BRAO describe ischemia affecting the retina, these diagnosis codes are appropriately assigned to MDC 02 (Diseases and Disorders of the Eye). The retina is a collection of cells at the back of the eye where the processing of visual information begins. Due to the retina's vital role in vision, damage to it can cause permanent blindness. The presence of CRAO or BRAO requires input from an ophthalmologist and treatment for these diagnoses would be expected to utilize different resources than a diagnosis of cerebral ischemia which may or may not involve visual impairment. Other possible interventions for CRAO or BRAO include attempting to lower the intraocular pressure with medication or by using a small-gauge needle to remove fluid to try to dislodge the embolus or ocular massage to dislodge the clot, which are not interventions generally performed for a diagnosis of acute ischemic stroke.

We stated in the FY 2023 IPPS/LTCH PPS proposed rule that to explore other mechanisms to address this request, we also reviewed claims data to consider the option of adding another severity level to the current structure of MS–DRG 123 (Neurological Eye Disorders) and assigning the cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent to the highest level. This option would have involved modifying the current base MS–DRG to a two-way severity level split or to a three-way severity level split of ''with MCC or thrombolytic agent, with CC, and without CC/MCC.'' Therefore, it would have included proposing new MS–DRGs if the data and our clinical advisors supported creation of new MS–DRGs. However, as displayed in the data findings in the table that follows, we found that the

data did not support this option. We applied the five criteria as described in section II.D.1.b. of the preamble of the proposed rule and this final rule to determine if it would be appropriate to subdivide cases currently assigned to MS–DRG 123 into severity levels. This analysis generally includes two years of MedPAR claims data to compare the data results from one year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. However, as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25092), our MS–DRG analysis last year was based on ICD–10 claims data from the March 2020 update of the FY 2019 MedPAR file, which contains hospital claims received from October 1, 2018 through March 31, 2020, for discharges occurring through September 30, 2019 and the ICD–10 claims data from the September 2020 update of the FY 2020 MedPAR file, which contains hospital claims received from October 1, 2019 through September 30, 2020, for discharges occurring through September 30, 2020 given the potential impact of the PHE for COVID–19. Therefore, for the FY 2023 IPPS/LTCH PPS proposed rule, we reviewed the claims data for base MS–DRG 123 using the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2022. We also reviewed the claims data for base MS–DRG 123 using the September 2021 update of the FY 2021 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2023. Our findings are shown in the table:

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases NonCC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs NonCC	Average Costs MCC/CC Combo	Average Costs CC/NonCC Combo
2021	2,642	374	1,220	1,048	$6,457	$8,605	$6,738	$5,364	$7,176	$6,103
2020	2,664	345	1,163	1,156	$5,943	$7,710	$6,235	$5,122	$6,573	$5,681
2019	3,100	376	1,393	1,331	$5,659	$8,276	$5,743	$4,832	$6,282	$5,298

We stated that we applied the criteria to create subgroups for the three-way severity level split. We referred the reader to section II.D.1.b. of the preamble of the FY 2023 IPPS/LTCH PPS proposed rule, for related discussion regarding our finalization of the expansion of the criteria to include the NonCC subgroup and our proposal to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split to maintain more stability in the current MS–DRG structure. We found that the criterion that there be at least 500 cases for each subgroup was not met, as shown in the table based on the data in the FY 2019, FY 2020, and FY 2021 MedPAR files. Specifically, for the ''with MCC'', ''with CC'', and ''without CC/MCC'' split, there were only 376 cases in the ''with MCC'' subgroup based on the data in the FY 2019 MedPAR file, only 345 cases in the ''with MCC'' subgroup based on the data in the FY 2020 MedPAR file and only 374 cases in the ''with MCC'' subgroup based on the data in the FY 2021 MedPAR file.

We then applied the criteria to create subgroups for the two-way severity level splits. For the ''with MCC'' and ''without MCC'' (CC+NonCC) split, the criterion that there be at least 500 cases for each subgroup failed due to low volume each year, specifically, for the ''with MCC'' subgroup as previously described. For the ''with CC/MCC'' and ''without CC/MCC'' (NonCC) split, we found that the criterion that there be at least a $2,000 difference in average costs between the ''with CC/MCC'' and ''without CC/MCC'' subgroups also failed. In the FY 2019 MedPAR file, our data analysis shows average costs in the hypothetical ''with CC/MCC'' subgroup of $6,282 and average costs in the hypothetical ''without CC/MCC'' subgroup of $4,832, for a difference of only $1,450 ($6,282 minus $4,832 = $1,450). In the FY 2020 MedPAR file, our data analysis shows average costs in the hypothetical ''with CC/MCC'' subgroup of $6,573 and average costs in the hypothetical ''without CC/MCC'' subgroup of $5,122, for a difference of only $1,451 ($6,573 minus $5,122 = $1,451). In the FY 2021 MedPAR file, our data analysis shows average costs in the hypothetical ''with CC/MCC'' subgroup of $7,176 and average costs in the hypothetical ''without CC/MCC'' subgroup of $5,364, for a difference of only $1,812 ($7,176 minus $5,364 = $1,812). We stated that our data analysis indicated that the current base MS–DRG 123 maintains the overall accuracy of the IPPS, and that the claims data did not support a three-way or a two-way severity level split for MS–DRG 123.

Lastly, we stated we explored reassigning cases with a principal diagnosis of CRAO or BRAO that receive the administration of a thrombolytic agent to other MS–DRGs within MDC 02. However, our review did not support reassignment of these cases to any other medical MS–DRGs as these cases would not be clinically coherent with the cases assigned to those other MS–DRGs.

Therefore, based on the various data analyses we performed to explore the possible reassignment of cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy, and the clinical analysis as previously discussed, for FY 2023 we did not propose any MS–DRG changes for cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy.

Comment: Some commenters expressed support for CMS' decision to not propose any MS–DRG changes for cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy.

Response: We appreciate the commenters' support.

Comment: Other commenters opposed or expressed concerns with CMS' decision to not propose any MS–DRG changes for cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy. These commenters stated from a pathophysiologic perspective, CRAO is the same process as a stroke of the brain and that the retina, although located within the eye, is a core component of the central nervous system and consists of brain cells (neurons) that also extend

through the entire course of the brain. These commenters also stated that the relationship of any particular tissue to its organ is related to its structure and function, and not its location. According to the commenters, acute CRAO is a medical emergency, equivalent to acute cerebral ischemic stroke, that needs to be treated in the same way with urgent inpatient evaluation, cerebrovascular and cardiac workup, and intervention. The commenters urged CMS to assign cases reporting diagnosis codes describing central retinal artery occlusion with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy to MS–DRGs 061, 062, and 063 to ensure appropriate payment for these cases.

Response: We thank the commenters for their feedback. Our clinical advisors reviewed the commenters' concerns and note that although commenters' state the relationship of any particular tissue to its organ is related to its structure and function, and not its location, in ICD–10, however, the body or organ system is the axis of the classification. By design, the patient characteristics included in the definition of each MS–DRG relate to a common organ system or etiology. Our clinical advisors agree with commenters that the retina is similar to the brain in terms of cellular and functional elements, but they note the retina is a part of the eye. Our clinical advisors state that the presence of CRAO or BRAO, which typically presents sudden, painless monocular loss of visual acuity and peripheral vision, requires input from an ophthalmologist which would not always be expected in a diagnosis of cerebral ischemia, which may or may not involve visual impairment. Our clinical advisors continue to believe CRAO and BRAO are appropriately classified with other eye conditions currently assigned to MDC 02.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal, without modification, to maintain the current assignment of cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy.

5. MDC 04 (Diseases and Disorders of the Respiratory System): Acute Respiratory Distress Syndrome (ARDS)

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28155 through 28156), we discussed a request we received to reassign cases reporting diagnosis code J80 (Acute respiratory distress syndrome) as the principal diagnosis from MS–DRG 204 (Respiratory Signs and Symptoms) to MS–DRG 189 (Pulmonary Edema and Respiratory Failure).

According to the requestor, when a patient presents with the condition of acute respiratory failure that progresses to acute respiratory distress syndrome (ARDS) during the hospital stay, official coding guidance instructs to only report the diagnosis code for ARDS (code J80). The requestor stated that in the American Hospital Association's (AHA) *Coding Clinic for ICD–10–CM and ICD–10–PCS,* Fourth Quarter 2020 publication, for a patient who is admitted in acute hypoxic respiratory failure that progresses to ARDS, the advice is to assign code J80, Acute respiratory distress syndrome. Additionally, in the ICD–10–CM Tabular List of Diseases, per the Excludes 1 note under category J96 (Respiratory failure, not elsewhere classified) only code J80 should be assigned when respiratory failure and ARDS are both documented. The same publication also maintained that ARDS is a life-threatening form of respiratory failure and is not an unrelated condition. Therefore, when acute respiratory failure is documented along with ARDS, only one code is reported to capture the highest level of severity.

The requestor also conveyed the Fourth Quarter 2020 publication's reference to previously published advice from the Fourth Quarter 2017 publication that stated, ''Acute respiratory distress syndrome (ARDS) is a life-threatening condition. ARDS is a rapidly progressive disorder that has symptoms of dyspnea, tachypnea, and hypoxemia. Fluid builds up in the alveoli and lowers the amount of oxygen that is circulated through the bloodstream. Low levels of oxygen in the blood threatens organ function. ARDS is often associated with sepsis, pneumonia, trauma and aspiration. The majority of people who develop ARDS are already in the hospital in critical condition from some other health complication. The focus of treatment is getting oxygen to the organs.''

We examined claims data from the September 2021 update of the FY 2021 MedPAR file for all cases in MS–DRG 204 and the cases reporting ARDS (code J80) as a principal diagnosis. Our findings are shown in the following table.

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
204	All Cases	5,241	2.8	$6,780
	Cases with principal diagnosis code J80 (Acute respiratory distress syndrome)	96	7.6	$15,077
	All other cases	5,145	2.7	$6,625

As shown in the table, the data demonstrate a longer average length of stay (7.6 days versus 2.8 days) and higher average costs ($15,077 versus $6,780) for the 96 cases reporting ARDS (code J80) as a principal diagnosis when compared to all 5,241 cases in MS–DRG 204.

We also examined claims data from the September 2021 update of the FY 2021 MedPAR file for all cases in MS–DRG 189. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
189	77,626	4.6	$9,780

We stated in the proposed rule that the data analysis supports that cases reporting ARDS (code J80) are more appropriately aligned with the average length of stay and average costs of the cases in MS–DRG 189 in comparison to MS–DRG 204 when ARDS is reported as a principal diagnosis. We also stated in the proposed rule that we agree, consistent with the coding clinic advice, ARDS is a life-threatening form of respiratory failure and the conventions of the ICD–10–CM classification as displayed in the Tabular List of Diseases Excludes note, support the concept that cases reporting ARDS as a principal diagnosis are more clinically coherent with the other conditions currently assigned to MS–DRG 189.

For these reasons, we proposed to reassign cases reporting ARDS (code J80) as a principal diagnosis from MS–DRG 204 to MS–DRG 189 effective FY 2023.

Comment: Commenters supported the proposal to reassign cases reporting diagnosis code J80 as a principal diagnosis from MS–DRG 204 to MS–DRG 189.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to reassign cases reporting ARDS (code J80) as a principal diagnosis from MS–DRG 204 to MS–DRG 189 effective FY 2023.

6. MDC 05 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Transluminal Coronary Angioplasty (PTCA) Logic

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28156 through 28157), we stated that we identified a replication issue from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs for procedure code 02UG3JE (Supplement mitral valve created from left atrioventricular valve with synthetic substitute, percutaneous approach) that was created effective October 1, 2016 (FY 2017), to identify and describe further interventions that may occur for a patient who had previously undergone cardiac valve surgery to correct a congenital anomaly, such as repair of a complete common atrioventricular canal defect.

As stated in the proposed rule, we used our established process in the assignment of new procedure code 02UG3JE to the most appropriate MS–DRG(s) for FY 2017. Procedure code 02UG3JE was proposed for assignment to the same MS–DRGs as its predecessor code. The predecessor code for procedure code 02UG3JE as shown in the 2017 ICD–10–PCS conversion table (available via the internet on the CMS web page at: *https://www.cms.gov/Medicare/Coding/ICD10/2017-ICD-10-PCS-and-GEMs*) is 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach). The ICD–9–CM comparable translation for this code (02UG3JZ) is procedure code 35.97 (Percutaneous mitral valve repair with implant), which identifies the use of the MitraClip® technology that has been discussed extensively in prior rulemaking.

In the FY 2017 rulemaking, using our established process, new procedure code 02UG3JE was proposed and finalized for assignment to the following MS–DRGs for FY 2017, as also shown in Table 6B.—New Procedure Codes in association with the FY 2017 IPPS/LTCH PPS proposed and final rules (available via the internet on the CMS web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download*). We noted that the listed MS–DRGs also reflect the MS–DRGs that the predecessor code (02UG3JZ) was assigned to at the time of the proposed rule.

MS-DRG	Description
231	Coronary Bypass with PTCA with MCC
232	Coronary Bypass with PTCA without MCC
233	Coronary Bypass with Cardiac Catheterization with MCC
234	Coronary Bypass with Cardiac Catheterization without MCC
235	Coronary Bypass without Cardiac Catheterization with MCC
236	Coronary Bypass without Cardiac Catheterization without MCC
273	Percutaneous Intracardiac Procedures with MCC
274	Percutaneous Intracardiac Procedures without MCC
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
982	Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC
983	Extensive O.R. Procedures Unrelated to Principal Diagnosis without CC/MCC

However, as also discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56809 through 56813), in connection with replication efforts between the ICD–9 and ICD–10 based MS–DRGs and the surgical hierarchy, the predecessor procedure code (02UG3JZ) was reassigned from MS–DRGs 273 and 274 to MS–DRG 228 (Other Cardiothoracic Procedures with MCC) and revised MS–DRG 229 (Other Cardiothoracic Procedures without MCC), and was removed from the PTCA logic for MS–DRGs 231 and 232. However, these proposed and finalized MS–DRG changes for procedure code 02UG3JZ were not considered for purposes of the MS–DRG assignments for new procedure code 02UG3JE, which were instead finalized as proposed based on the existing MS–DRG assignments for the predecessor code, and code 02UG3JE continued to remain on the

PTCA list in the GROUPER logic for MS–DRGs 231 and 232.

As noted in the proposed rule, our clinical advisors stated that procedure code 02UG3JE does not describe a PTCA procedure. As also noted in the proposed rule, we analyzed claims data from the September 2021 update of the FY 2021 MedPAR file for cases in MS–DRGs 231 and 232 to determine if there were any cases reported with procedure code 02UG3JE, and there were no such cases found.

Accordingly, because the procedure described by procedure code 02UG3JE is not clinically consistent with a PTCA procedure and it was initially assigned to the list for PTCA procedures in the GROUPER logic as a result of replication in the transition from ICD–9 to ICD–10 based MS–DRGs, we proposed to remove procedure code 02UG3JE from the list for PTCA procedures in the GROUPER logic for MS–DRGs 231 and 232 effective FY 2023. We also proposed to maintain the MS–DRG assignment for procedure code 02UG3JE in MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCC, respectively) for FY 2023.

Comment: Commenters agreed with the proposal to remove procedure code 02UG3JE from the GROUPER logic for MS–DRGs 231 and 232 and to maintain the assignment in MS–DRGs 266 and 267.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove procedure code 02UG3JE from the list for PTCA procedures in MS–DRGs 231 and 232 and to maintain the assignment for code 02UG3JE in MS–DRGs 266 and 267 in the GROUPER logic for FY 2023.

b. Neuromodulation Device Implant for Heart Failure (Barostim™ Baroreflex Activation Therapy)

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28157 through 28162), the BAROSTIM NEO™ System is the first neuromodulation device system designed to trigger the body's main cardiovascular reflex to target symptoms of heart failure. The system consists of an implantable pulse generator (IPG) that is implanted subcutaneously in the upper chest below the clavicle, a stimulation lead that is sutured to either the right or left carotid sinus to activate the baroreceptors in the wall of the carotid artery and a wireless programmer system that is used to non-invasively program and adjust BAROSTIM NEO™ therapy via telemetry. The BAROSTIM NEO™ System is indicated for the improvement of symptoms of heart failure in a subset of patients with symptomatic New York Heart Association (NYHA) class II and III heart failure with low cardiac ejection fractions who do not benefit from guideline directed pharmacologic therapy or qualify for Cardiac Resynchronization Therapy (CRT).

The BAROSTIM NEO™ System was approved for new technology add-on payments for FY 2021 (85 FR 58716 through 58717) and FY 2022 (86 FR 44974). We refer readers to section II.F.5.a of the preamble of the proposed rule and this final rule for a discussion regarding the FY 2023 status of technologies approved for FY 2022 new technology add-on payments, including the BAROSTIM NEO™ System.

For the FY 2023 IPPS/LTCH PPS proposed rule, we received a request to (1) reassign the ICD–10–PCS procedure codes that describe the implantation of the BAROSTIM NEO™ System from MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC, without MCC respectively) to MS–DRGs 222, 223, 224, 225, 226, and 227 (Cardiac Defibrillator Implant with and without Cardiac Catheterization with and without AMI/HF/Shock with and without MCC, respectively) and (2) reassign the procedure code that describes the placement of a BAROSTIM NEO™ IPG alone from MS–DRGs 252, 253 and 254 to MS–DRG 245 (AICD Generator Procedures).

We stated in the FY 2023 IPPS/LTCH PPS proposed rule that the following ICD–10–PCS procedure codes uniquely identify the implantation of the BAROSTIM NEO™ System: 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HK3MZ (Insertion of stimulator lead into right internal carotid artery, percutaneous approach) or 03HL3MZ (Insertion of stimulator lead into left internal carotid artery, percutaneous approach). The requestor noted that ICD–10–PCS codes 0JH60MZ, 03HK3MZ and 03HL3MZ are individually assigned to MDC 05 in MS–DRGs 252, 253, and 254 but not mapped to the logic of these MS–DRGs in a code combination or code cluster. According to the requestor this means that cases with a principal diagnosis from MDC 05 with procedure codes describing the implantation of a BAROSTIM NEO™ system (0JH60MZ with 03HL3MZ or 03HK3MZ); with procedure codes describing placement of the stimulator generator alone (0JH60MZ); or with procedure codes describing the placement of a carotid sinus lead only (03HL3MZ or 03HK3MZ) are all assigned to MS–DRGs 252, 253, and 254, despite the significant differences in the clinical coherence and resources required to perform these distinct procedures.

The requestor stated that cases reporting procedure codes describing the implantation of a BAROSTIM NEO™ system are more clinically similar to, and have costs that are more closely aligned to, cases within MS–DRGs 222, 223, 224, 225, 226, and 227. The requestor stated that according to its own analysis, the population of Medicare patients surgically treated with procedures assigned to MS–DRGs 222, 223, 224, 225, 226, and 227 is essentially identical to the population treated with the BAROSTIM NEO™ System. According to the requestor, this congruent patient population accounts for essentially all cases assigned to MS–DRGs 222, 223, 224, 225, 226, and 227. The requestor stated their analysis demonstrated that over 80% of the cases in MS–DRGs 222, 223, 224, 225, 226, and 227 had a diagnosis of heart failure, compared to only 30% of cases with a diagnosis of heart failure assigned to MS–DRGs 252, 253, and 254. The requestor stated that the subset of patients that have an indication for the implantation of a BAROSTIM NEO™ system also have indications for the implantation of Implantable Cardioverter Defibrillators (ICD), Cardiac Resynchronization Therapy Defibrillators (CRT–D) and/or Cardiac Contractility Modulation (CCM) devices, all of which also require the permanent implantation of a programmable, electrical pulse generator and at least one electrical lead. The requestor specifically highlighted that the procedure code combinations describing the implantation of a cardiac contractility modulation (CCM) device system, which consists of a programmable implantable pulse generator (IPG) and three leads, one of which is implanted into the right atrium and the other two leads which are inserted into the right ventricle is assigned to MS–DRGs 222, 223, 224, 225, 226, and 227, and the codes describing the insertion of contractility modulation device generator alone are assigned to MS–DRG 245. The requestor stated that the average resource utilization required to implant the BAROSTIM NEO™ System demonstrates a significant disparity compared to all procedures within MS–DRGs 252, 253, and 254 and noted that the cost of the BAROSTIM NEO™ implantable device is $35,000, which is in range with the cost of the other

cardiac implantable devices (for example ICD, CRT–D, and CCM) assigned to MS–DRGs 222, 223, 224, 225, 226, and 227.

The requestor stated that the majority of the procedures assigned to MS–DRGs 252, 253, and 254 are primarily designed to identify, diagnose, clear and restructure veins and arteries, excluding those that require implantable devices. Furthermore, the requestor stated the surgical procedures within MS–DRGs 252, 253, and 254 are not intended to treat or improve the function of the heart, nor treat the symptoms of heart failure.

The requestor acknowledged that there are very few cases within the publicly available Medicare inpatient claims data that potentially includes procedure codes describing the implantation of a BAROSTIM NEO™ system. The requestors' own analysis revealed fewer than 11 cases with procedure codes describing the implantation of a BAROSTIM NEO™ system in the combined FY 2019 and FY 2020 MedPAR data and noted that during much of this time period, the BAROSTIM NEO™ System was only implanted as part of a controlled clinical trial. The requestor stated that this incomplete data should not be used to determine initial MS–DRG assignments, especially for new FDA designated 'breakthrough' medical technologies like the BAROSTIM NEO™ system. Rather, the requestor stated that CMS should use available information and expert knowledge to make initial MS–DRG assignments, while waiting for a substantial number of Medicare covered, post-approved claims from a disperse set of hospitals to reconsider MS–DRG assignments as necessary. The requestor cautioned that upon new technology add-on payments expiration, and if the inadequate MS–DRG assignment for these procedures continues, inpatient admissions to implant the BAROSTIM NEO™ system will be paid less than outpatient admissions to perform the same procedures.

The ICD–10–CM diagnosis codes that describe heart failure are found in the following table. These diagnosis codes are all currently assigned to MDC 05.

ICD-10-CM Code	Description
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery

We stated in the proposed rule that first, we examined claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 252, 253 and 254 to identify cases reporting a diagnosis of heart failure and procedure codes describing the implantation of the BAROSTIM NEO™ system with or without a procedure code describing the performance of a cardiac catheterization as MS–DRGs 222, 223, 224, 225, 226, and 227 are defined by the performance of cardiac catheterization. Our findings are shown in the following table.

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
252	All cases	24,839	7.6	$27,488
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ with cardiac catheterization	0		
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ without cardiac catheterization	2	4.5	$67,588
253	All cases	18,373	5.2	$21,978
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ with cardiac catheterization	0		
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ without cardiac catheterization	1	1	$19,237

As shown in the table, the data analysis performed indicates that the two cases in MS–DRG 252 reporting procedure codes describing the implantation of a BAROSTIM NEO™ system have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 252 (4.5 days versus 7.6 days) and higher average costs when compared to all the cases in MS–DRG 252 ($67,588 versus $27,488). These two cases did not also report a procedure code describing the performance of a cardiac catherization. The one case in MS–DRG 253 reporting procedure codes describing the implantation of a BAROSTIM NEO™ system had a length of stay that is shorter than the average length of stay for all the cases in MS–DRG 253 (1 day versus 5.2 days) and lower costs when compared to all the cases in MS–DRG 253 ($19,237 versus $21,978). This case did not also report a procedure code describing the performance of a cardiac catherization. We found zero cases in MS–DRG 254 reporting procedure codes describing the implantation of a BAROSTIM NEO™ system.

We stated that our clinical advisors reviewed this data and noted that was it is difficult to detect patterns of complexity and resource intensity based on the three cases that reported procedure codes describing the implantation of a BAROSTIM NEO™ system. The claims data also reflect a wide variance with regard to the length of stay and average costs for the three cases that did report the implantation of a BAROSTIM NEO™ system. We stated that the results of the claims analysis demonstrated we did not have sufficient claims data on which to base and evaluate any proposed changes to the current MS–DRG assignment. We also stated that our clinical advisors also expressed concern in equating the implantation of a BAROSTIM NEO™ system to the placement of ICD, CRT–D, and CCM devices as these devices all differ in terms of technical complexity and anatomical placement of the electrical lead(s). Our clinical advisors noted there is no intravascular component or vascular puncture involved when implanting a BAROSTIM NEO™ system. Our clinical advisors also noted the placement of ICD, CRT–D, and CCM devices generally involve a lead being affixed to the myocardium, being threaded through the coronary sinus or crossing a heart valve and are procedures that involve a greater level of complexity than affixing the stimulator lead to either the right or left carotid sinus when implanting a BAROSTIM NEO™ system.

Next, to evaluate the request to reassign the procedure code that describes the placement of a BAROSTIM NEO™ IPG alone from MS–DRGs 252, 253 and 254 to MS–DRG 245 (AICD Generator Procedures), we stated in the proposed rule that we examined claims data from the September 2021 update of the FY 2021 MedPAR file for all cases in MS–DRGs 252, 253 and 254 and compared the results to cases with a procedure code describing placement of the stimulator generator alone. Our findings are shown in the following table.

MS-DRGs 252-254: Cases Reporting Procedures Describing Placement of a BAROSTIM NEO™ Stimulator Generator

MS-DRG	ICD-10-PCS codes	Number of Cases	Average Length of Stay	Average Costs
252	All cases	24,839	7.6	$27,488
	Cases with procedure code 0JH60MZ alone	12	8.8	$56,622
253	All Cases	18,373	5.2	$21,978
	Cases with procedure code0JH60MZ alone	4	2.5	$30,451

As shown in the table, the data analysis performed indicates that the 12 cases in MS–DRG 252 reporting a procedure code describing placement of the stimulator generator alone have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 252 (8.8 days versus 7.6 days) and higher average costs when compared to all the cases in MS–DRG 252 ($56,622 versus $27,488). The four cases in MS–DRG 253 reporting a procedure code describing placement of the stimulator generator alone have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 253 (2.5 days versus 5.2 days) and higher average costs when compared to all the cases in MS–DRG 253 ($30,451 versus $21,978). We found zero cases in MS–DRG 254 reporting a procedure code describing placement of the stimulator generator alone.

We stated that our clinical advisors reviewed this data, and found, similar to the analysis of the data from the three cases that reported procedure codes describing the implantation of a BAROSTIM NEO™ system, that it was difficult to detect patterns of complexity and resource intensity based on the few cases that reported procedure codes describing placement of the stimulator generator alone. The claims data similarly reflects a wide variance with regard to the length of stay and average costs for these cases that did report the placement of the stimulator generator alone, indicating there may have been other factors contributing to the higher costs. When reviewing the consumption of hospital resources for this small subset of cases, the claims data also suggest that the increased costs may be attributable to the severity of illness of the patient and other circumstances of the admission as the patients tended to have a major complication or co-morbid (MCC) condition reported based on the MS–DRG assigned.

We stated in the proposed rule that we recognized the average costs of the small numbers of cases reporting a procedure code describing placement of the stimulator generator alone are greater when compared to the average costs of all cases in their respective MS–DRG. We noted that the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We further noted that section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs.

In response to the requestor's concerns regarding procedures currently assigned to MS–DRGs 252, 253 and 254, as discussed in section II.D.3.b. of the preamble of the proposed rule and this final rule, we note that MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) are examples of the ''other'' surgical class, and therefore it is expected that there will be procedures not as precisely clinically aligned within the definition (logic) of these MS–DRGs. In regard to the concern about the implications for reimbursement when these procedures are performed in the outpatient setting as opposed to the inpatient setting, we noted that the goals of reviewing the MS–DRG assignments of particular procedures are to better clinically represent the resources involved in caring for these patients and to enhance the overall accuracy of the system.

In the proposed rule, in response to the requestor's statement that CMS should use available information and expert knowledge to make initial MS–DRG assignments, while waiting for a substantial number of Medicare covered, post-approved claims from a disperse set of hospitals to reconsider MS–DRG assignments as necessary, we noted that we use our established process for GROUPER assignments for new diagnosis and procedure codes. Specifically, consistent with our established process for assigning new diagnosis and procedure codes, we stated that we review the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We noted that this process will not automatically result in the new diagnosis or procedure code being assigned to the same MS–DRG or having the same designation as the predecessor code. Members of the public have the opportunity to provide feedback on the assignment and designation of the codes if they disagree. We referred the reader to section II.D.17 of the proposed rule for a more detailed discussion of this process. We noted that when BAROSTIM NEO™ applied for new technology add-on payment, it was noted that the technology could be uniquely identified using a combination of existing ICD–10–PCS codes that were already assigned to MS–DRGs, and this circumstance generally would not provide a basis for MS–DRG reassignment.

Lastly, as discussed in the proposed rule, our clinical advisors expressed concern regarding making proposed MS–DRG changes based on a specific, single technology (BAROSTIM NEO™ system), identified by only one unique procedure code combination versus considering proposed changes based on a group of related procedure codes that can be reported to describe that same type or class of technology, which is more consistent with the intent of the MS–DRGs.

We stated that we believed that as the number of cases reporting procedure codes describing the implantation of neuromodulation devices for heart failure increases, a better view of the associated costs and lengths of stay on average will be reflected in the data for purposes of assessing any reassignment of these cases. We indicated that our clinical advisors stated that it would not be appropriate to reassign cases for patients from MS–DRGs 252, 253 and 254 to MS–DRGs 222, 223, 224, 225, 226, and 227 in the absence of additional data to better determine the resource utilization for this subset of patients to help inform whether a reassignment would be clinically warranted. Therefore, for the reasons stated previously, we proposed to maintain the assignment of cases reporting procedure codes that describe the implantation of a neuromodulation device in MS–DRGs 252, 253 and 254 for FY 2023. We also proposed to maintain the assignment of cases reporting a procedure code describing placement of a stimulator generator alone in MS–DRGs 252, 253 and 254 for FY 2023.

Comment: Commenters expressed support for CMS' proposal to maintain the assignment of cases reporting procedure codes that describe the implantation of a neuromodulation device for heart failure in MS–DRGs 252, 253 and 254 and to maintain the assignment of cases reporting a procedure code describing placement of a stimulator generator alone in MS–DRGs 252, 253 and 254 for FY 2023.

Response: We appreciate the commenters' support.

Comment: A commenter opposed CMS' proposal. The commenter stated that in their own analysis of the MedPAR data, and from their real-world experience, patients with an indication for implantation of a neuromodulation device were not always admitted with a heart failure diagnosis. Many patients presented with multiple comorbidities, and various cardiovascular diagnosis

(for example, syncope, tachycardia, atrial fibrillation etc.) which lead to heart failure or are concomitant with heart failure.

This commenter further stated that in their review of the data that CMS presented, the cost of cases with a diagnosis of heart failure with procedure codes describing the implantation of a neuromodulation device without cardiac catheterization and the cost of cases with a procedure code describing placement of the stimulator generator alone are both more than twice that of all cases in MS–DRG 252. The commenter stated even given these disparities, they did not believe that the full costs of the implantation of a neuromodulation device system have been appreciated in the MedPAR data files. According to the commenter, the manufacturer did not charge a cost for the device during clinical trials for the BAROSTIM NEO™ so such claims do not reflect the full device cost. The commenter also stated that the COVID–19 pandemic has had a negative impact on inpatient hospital uptake of this new technology, which in turn has also limited the data available to support an accurate and appropriate MS–DRG assignment. The commenter stated they believe the fact that there are few cases in the MedPAR data files to date is not a reason to allow an overly mispriced MS–DRG assignment. The commenter stated that while BAROSTIM NEO™ procedures are typically performed in the outpatient setting, it is important to preserve inpatient access for those patients with comorbidities or other risk factors that necessitate an inpatient level of care. According to this commenter, the current MS–DRG assignments for procedure codes that describe the implantation of a neuromodulation device for heart failure would result in a lower payment than procedures performed in the outpatient setting and could result in barriers to treatment for patients who are not suitable candidates for the outpatient setting.

This commenter urged CMS to reassign the ICD–10–PCS procedure codes that describe the implantation of a neuromodulation device for heart failure from MS–DRGs 252, 253 and 254 to MS–DRGs 222, 223, 224, 225, 226 and 227 as requested. As alternatives, the commenter recommended to CMS, to instead, consider reassigning the ICD–10–PCS procedure codes that describe the implantation of the BAROSTIM NEO™ System from MS–DRGs 252, 253 and 254 to MS–DRGs 270, 271 and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively) or even create a new MS–DRG that appropriately describes these procedures.

Response: We appreciate the commenter's feedback and concern. With regard to the commenter's concern that patients with an indication for the implantation of neuromodulation devices are not always admitted with heart failure diagnoses, we wish to confirm that the examination of claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 252, 253 and 254 to identify cases reporting a diagnosis of heart failure and procedure codes describing the implantation of neuromodulation devices for heart failure with or without a procedure code describing the performance of a cardiac catheterization, as discussed in the proposed rule, included cases reporting a diagnosis of heart failure as either a principal or secondary diagnosis.

Our clinical advisors reviewed commenter's concerns and continue to note we do not have sufficient claims data on which to base and evaluate any proposed changes to the current MS–DRG assignment, given the difficulties of assessing patterns of complexity and resource intensity based on the limited number of cases identified. Our clinical advisors also continue to express concern in equating the implantation of neuromodulation devices for heart failure to the placement of ICD, CRT–D, and CCM devices as these devices all differ in terms of technical complexity and anatomical placement of the electrical lead(s), as discussed in the proposed rule. In regard to the concern about the implications for payment when these procedures are performed in the outpatient setting as opposed to the inpatient setting, as noted in the proposed rule, and in prior rulemaking, the goals of reviewing the MS–DRG assignments of particular procedures are to better clinically represent the resources involved in caring for these patients and to enhance the overall accuracy of the system.

With regard to the commenter's concern that there may have been other contributing factors that limited the data available to support an accurate and appropriate MS–DRG assignment of these cases, our clinical advisors believe that as the number of cases reporting procedure codes describing the implantation of neuromodulation devices for heart failure increases, the associated resource utilization can be better assessed for purposes of evaluating any reassignment of these cases. As additional claims data becomes available, we will continue to analyze the clinical nature of procedure codes describing the implantation of neuromodulation devices for heart failure and their MS–DRG assignments, including potential alternative MS–DRG assignments, to further improve the overall accuracy of the IPPS payments in future rulemaking.

Therefore, after consideration of the public comments we received, and for the reasons stated earlier, we are finalizing our proposal to maintain the assignment of cases reporting procedure codes that describe the implantation of a neuromodulation device in MS–DRGs 252, 253 and 254, without modification, for FY 2023. We are also finalizing our proposal to maintain the assignment of cases reporting a procedure code describing placement of a stimulator generator alone in MS–DRGs 252, 253 and 254, without modification, effective October 1, 2022 for FY 2023.

In the proposed rule, we also noted that during our review of this issue, as we examined the GROUPER logic that would determine an assignment of a case to MS–DRGs 222, 223, 224, 225, 226, and 227, we found two diagnosis codes describing heart failure that are not currently in the listed principal diagnoses in the GROUPER logic for MS–DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or Shock with and without MCC, respectively). These diagnosis codes are listed in the following table.

ICD-10-CM Code	Description
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery

We stated that as a result, when either of these codes are coded as a principal diagnosis, MS–DRGs 224 and 225 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI, HF, or Shock with and without MCC, respectively) are instead assigned when reported with a procedure code combination describing the implantation of a cardiac defibrillator and a procedure describing the performance of a cardiac catherization procedure. We referred the reader to the ICD–10 MS–DRG Definitions Manual Version 39.1, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 222, 223, 224, and 225.

In the proposed rule, we stated that our clinical advisors reviewed this issue and believed that cases reporting diagnosis code I97.130 or I97.131 as a principal diagnosis are associated with a severity of illness on par with cases reporting a principal diagnosis of a type of heart failure. We noted that in order to code postprocedural heart failure in ICD–10–CM, instructional notes at category I50 direct to ''code first heart failure following surgery'' (that is, I97.130 and I97.131) with a second code from subcategory of I50 listed after the postprocedural heart failure code to specify the type of heart failure. We stated that our clinical advisors recommended adding diagnosis codes I97.130 and I97.131 to the logic list of principal diagnoses that describe heart failure for clinical consistency, recognizing that coding guidelines instruct to code I97.130 and I97.131 before the codes from subcategory of I50 that specify the type of heart failure, as the codes from subcategory of I50 are currently in the listed principal diagnoses in the GROUPER logic for MS–DRGs 222 and 223. Therefore, we proposed to modify the GROUPER logic to allow cases reporting diagnosis code I97.130 or I97.131 as a principal diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures.

Comment: Commenters expressed support for CMS' proposal to modify the GROUPER logic to allow cases reporting diagnosis code I97.130 or I97.131 as a principal diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to modify the GROUPER logic to allow cases reporting diagnosis code I97.130 or I97.131 as a principal diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures, without modification, effective October 1, 2022 for FY 2023.

c. Cardiac Mapping

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28162 through 28163), we identified a replication issue from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs for procedure code 02K80ZZ (Map conduction mechanism, open approach). Cardiac mapping describes the creation of detailed maps to detect how the electrical signals that control the timing of the heart rhythm move between each heartbeat to identify the location of rhythm disorders. Cardiac mapping is generally performed during open-heart surgery or performed via cardiac catherization.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49363 through 49369), we discussed a request to remove the cardiac ablation and other specified cardiovascular procedures from the following MS–DRGs, and to create new MS–DRGs to classify these procedures:

- MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS–DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC);
- MS–DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS–DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC);
- MS–DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC); and
- MS–DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC).

The requestor recommended that CMS assign the following ICD–9–CM procedure codes that identify and describe cardiac ablation procedures and the other percutaneous intracardiac procedures to the newly created MS–DRGs:

- 35.52 (Repair of atrial septal defect with prosthesis, closed technique);
- 35.96 (Percutaneous balloon valvuloplasty);
- 35.97 (Percutaneous mitral valve repair with implant);
- 37.26 (Catheter based invasive electrophysiologic testing);
- 37.27 (Cardiac mapping);
- 37.34 (Excision or destruction of other lesion or tissue of heart, endovascular approach);
- 37.36 (Excision, destruction, or exclusion of left atrial appendage (LAA)); and
- 37.90 (Insertion of left atrial appendage device).

We stated we agreed that creating these new MS–DRGs would better reflect utilization of resources and clinical cohesiveness for intracardiac procedures in comparison to intracoronary procedures. Therefore, after consideration of the public comments we received, we finalized our proposal to create MS–DRGs 273 (Percutaneous Intracardiac Procedures with MCC) and MS–DRG 274 (Percutaneous Intracardiac Procedures without MCC) for the FY 2016 ICD–10 MS–DRGs Version 33 and finalized the assignment of the procedures performed within the heart chambers using intracardiac techniques to the two new MS–DRGs.

In the FY 2016 rulemaking, we stated that the comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.27 (Cardiac mapping) were ICD–10–PCS codes 02K83ZZ (Map conduction mechanism, percutaneous approach) and 02K84ZZ (Map conduction mechanism, percutaneous endoscopic approach). However, code 02K80ZZ (Map Conduction Mechanism, Open Approach), which is also a comparable ICD–10–PCS code translation for ICD–9–CM procedure code 37.27, was inadvertently excluded. Consequently, procedure code 02K80ZZ continued to remain in the GROUPER logic for MS–DRGs 246, 247, 248, 249, 250 and 251.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58477), we finalized a revision to the titles for MS–DRGs 273 and 274 to ''Percutaneous and Other Intracardiac Procedures with and without MCC, respectively'' to better reflect the procedures assigned to them.

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, in the ICD–10 MS–DRGs Definitions Manual Version 39.1, procedure code 02K80ZZ is currently recognized as a non-O.R. procedure that affects the MS–DRG to which it is assigned. We stated that our clinical advisors reviewed this grouping issue and stated that procedure code 02K80ZZ does not describe a percutaneous cardiovascular procedure. We stated that our clinical advisors supported the reassignment of code 02K80ZZ for clinical coherence, noting the procedure should be appropriately grouped along with other procedure codes that describe cardiac mapping currently assigned to MS–DRGs 273 and

274. Accordingly, because the procedure described by procedure code 02K80ZZ is not clinically consistent with percutaneous cardiovascular procedures and it was initially assigned MS–DRGs 246, 247, 248, 249, 250 and 251 as a result of replication in the transition from ICD–9 to ICD–10 based MS–DRGs, we proposed the reassignment of procedure code 02K80ZZ from MS–DRGs 246, 247, 248, 249, 250 and 251 to MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively) in MDC 05 effective FY 2023.

As discussed in section II.D.1.b of the preamble of the proposed rule, we noted that we were providing a test version of the ICD–10 MS–DRG GROUPER Software, Version 40, so that the public could better analyze and understand the impact of the proposals included in the proposed rule. We noted that at the time of the development of the test software this issue was unable to be addressed and therefore, it did not reflect the proposed reassignment of procedure code 02K80ZZ from MS–DRGs 246, 247, 248, 249, 250 and 251 to MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively) in MDC 05 for Version 40.

Comment: Commenters agreed with our proposal to reassign procedure code 02K80ZZ from MS–DRGs 246, 247, 248, 249, 250 and 251 to MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively). A few commenters stated that they appreciate CMS identifying a replication issue from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs and supported the reassignment of procedure code 02K80ZZ. A commenter agreed that cardiac mapping is generally performed during open-heart surgery or performed via cardiac catheterization to create detailed maps of electrical signals to identify the location of rhythm disorders.

Response: We thank the commenters for their support.

Comment: Other commenters opposed the proposal. Several commenters noted that CMS stated that code 02K80ZZ affects the MS–DRG to which it is assigned, however, based on their review of the MS–DRG logic, code 02K80ZZ is designated as a non-O.R procedure and does not affect MS–DRG assignment. Other commenters expressed concern that data was not analyzed to see if code 02K80ZZ had been found in MS–DRGs 246, 247, 248, 249, 250 and 251. A commenter stated that should it be determined that code 02K80ZZ had not been found in MS–DRGs 246, 247, 248, 249, 250 and 251, then they agreed with removal of code 02K80ZZ from these MS–DRGs and reassignment to MS–DRGs 273–274. However, should the analysis show code 02K80ZZ assigned to MS–DRGs 246, 247, 248, 249, 250 and 251, this commenter suggested CMS consider if the assignment of code 02K80ZZ to these MS–DRGs should be maintained, and if not, what ramifications the reassignment would have.

A few commenters recommended that CMS consider assigning code 02K80ZZ to MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) instead. Some commenters stated that they believe that procedures to map conduction mechanism share similar clinical and resource consumption as the surgical ablation procedures performed via an open approach that are currently assigned to MS–DRGs 228 and 229. These commenters further stated that given that 02K80ZZ (Map conduction mechanism, open approach) does not describe a percutaneous cardiovascular procedure, they did not recommend the assignment of the code to MS–DRGs 273 and 274. A commenter stated that based on their own analysis, 02K80ZZ is more often assigned to MS–DRGs 228 and 229 than to MS–DRGs 273 and 274, and furthermore, the ICD–10–PCS codes included in MS–DRGs 273 and 274 are ablation procedures via percutaneous approach. Another commenter asserted that the procedures in MS–DRGs 273 and 274 are all percutaneous approach procedures.

Response: We thank the commenters for their feedback.

We note that in the ICD–10 MS–DRGs Definitions Manual Version 39.1, procedure code 02K80ZZ is in fact recognized as a non-O.R. procedure affecting MS–DRGs 246, 247, 248, 249, 250 and 251, specifically. Under the IPPS MS–DRGs, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS–DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). For each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non O.R. affecting the MS–DRG'' because these procedure codes describe procedures that would generally require a greater intensity of resources for facilities to manage the cases included in the definition (logic) of these MS–DRGs. We refer readers to the ICD–10 MS–DRG Version 39.1 Definitions Manual at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index. Procedures designated as ''non O.R. affecting the MS–DRG'' are listed in Appendix E with an asterisk.

In response to the comments expressing concern that data was not analyzed to determine if there were any cases reported with procedure code 02K80ZZ in MS–DRGs 246, 247, 248, 249, 250 and 251, we refer the reader to Table 6P.1e associated with this final rule and available via the internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. This table displays the findings from our analysis of the claims data from the September 2021 update of the FY 2021 MedPAR file to determine if there were any cases reported with procedure code 02K80ZZ assigned to MS–DRGs 246, 247, 248, 249, 250 and 251 and reflects that there were no such cases found.

With regard to the commenters' concerns that procedures to map conduction mechanism share similar clinical and resource consumption as surgical ablation procedures performed via an open approach, our clinical advisors note that while cardiac mapping can be used to identify and localize areas responsible for rhythm disturbances to serve as a target for surgical ablation, each of these procedures are defined by clinically distinct definitions and objectives, which is why there are separate and unique ICD–10–PCS procedure codes within the classification for reporting purposes. Our clinical advisors note that cardiac mapping describes the creation of detailed maps, generally involving the use of electrodes and a mapping system (consisting of amplifiers and a recording and analysis system), to detect how the electrical signals that control the timing of the heart rhythm move between each heartbeat to identify the location of rhythm disorders. Surgical ablation, however, describes the burning or freezing of tissue on the inside of the heart to disrupt faulty electrical signals causing the arrhythmia.

We also note in response to the comments received that percutaneous ablation procedures are not the only procedures assigned to MS–DRGs 273 and 274. Of note, left atrial appendage closure (LAAC) procedures, with and without an implant, are also assigned to MS–DRGs 273 and 274. In response to the commenters who did not agree with the proposal to reassign procedure code 02K80ZZ from MS–DRGs 246, 247, 248, 249, 250 and 251 to MS–DRGs 273 and 274 based on the open approach of the procedure, as noted in the proposed rule, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58477), we finalized a revision to the titles for MS–DRGs 273 and 274 to ''Percutaneous and Other Intracardiac Procedures with and without MCC, respectively'' to better reflect the procedures assigned, as not only percutaneous procedures are assigned to these MS–DRGs. We refer the reader to the ICD–10 MS–DRG Definitions Manual, version 39.1, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 273 and 274.

Our clinical advisors continue to note that code 02K80ZZ (Map Conduction Mechanism, Open Approach), which is a comparable ICD–10–PCS code translation for ICD–9–CM procedure code 37.27 (Cardiac mapping), was inadvertently excluded in FY 2016 rulemaking when we finalized our proposal to create MS–DRGs 273 and MS–DRG 274 to better reflect utilization of resources and clinical cohesiveness for intracardiac procedures in comparison to intracoronary procedures. Our clinical advisors continue to support the reassignment of code 02K80ZZ for clinical coherence, noting the procedure should be appropriately grouped along with other procedure codes that describe cardiac mapping that are currently assigned to MS–DRGs 273 and 274.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to reassign procedure code 02K80ZZ from MS–DRGs 246, 247, 248, 249, 250 and 251 to MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively) in MDC 05 for Version 40, without modification.

d. Surgical Ablation

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44836 through 44848), we discussed a two-part request we received to review the MS–DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation. The first part of the request was to create a new classification of surgical ablation MS–DRGs to better accommodate the costs of open concomitant surgical ablations. The requestor identified the following potential procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure.

- Open CABG + open surgical ablation
- Open MVR + open surgical ablation
- Open AVR + open surgical ablation
- Open MVR + open AVR + open surgical ablation
- Open MVR + open CABG + open surgical ablation
- Open MVR + open AVR + open CABG + open surgical ablation
- Open AVR + open CABG + open surgical ablation

As discussed in the FY 2022 IPPS/LTCH PPS final rule, we examined claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting procedure code combinations describing open concomitant surgical ablations. We refer the reader to Table 6P.1o associated with the FY 2022 final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for data analysis findings of cases reporting procedure code combinations describing open concomitant surgical ablations. We stated our analysis showed while the average lengths of stay and average costs of cases reporting procedure code combinations describing open concomitant surgical ablations are higher than all cases in their respective MS–DRG, we found variation in the volume, length of stay, and average costs of the cases. We also stated findings from our analysis indicated that MS–DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) as well as approximately 31 other MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. We refer the reader to section II.D.1.b. of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44796 through 44798), for related discussion regarding our finalization of the proposal to delay application of the NonCC subgroup criteria to existing MS–DRGs with three-way severity level split to maintain more stability in the current MS–DRG structure.

In the FY 2022 final rule, we finalized our proposal to revise the surgical hierarchy for the MS–DRGs in MDC 05 (Diseases and Disorders of the Circulatory System) to sequence MS–DRGs 231–236 (Coronary Bypass) above MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively), effective October 1, 2021. In addition, we also finalized the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS–DRGs 233 and 234 and changed the titles of these MS–DRGs to ''Coronary Bypass with Cardiac Catheterization or Open Ablation with and without MCC, respectively'' to reflect this reassignment for FY 2022.

In response to this final policy, as discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28163), we received a request to again review the MS–DRG assignment of cases involving open concomitant surgical ablation procedures. The requestor stated they continue to believe that the average hospital costs for surgical ablation for atrial fibrillation demonstrates a cost disparity compared to all procedures within their respective MS–DRGs. The requestor suggested that when open surgical ablation is performed with MVR, or AVR or MVR/AVR + CABG that these procedures are either (1) assigned to a different family of MS–DRGs or (2) assigned to MS–DRGs 216 and 217 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC and with CC, respectively) similar to what CMS did with CABG and open ablation procedures in the FY 2022 rulemaking to better accommodate the added cost of open concomitant surgical ablation.

In the proposed rule we stated the change to the surgical hierarchy in MDC 05 and the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS–DRGs 233 and 234 is recent, only becoming effective October 1, 2021. We stated that we believed more time was needed before considering to again review the MS–DRG assignment of cases reporting procedure code combinations describing open concomitant surgical ablations as the data from the September 2021 update of the FY 2021 MedPAR file does not reflect our FY 2022 finalization. In addition, our clinical advisors continued to state that in open concomitant surgical ablation procedures, the CABG, MVR, and AVR components of the procedure are more technically complex than the open surgical ablation procedure. They also stated that the finalized revision to the

surgical hierarchy leads to a grouping that is more coherent and better accounts for the resources expended to address the more complex procedures from other cases redistributed during the hierarchy change. As noted, we stated that we believed that additional time was needed to allow for further analysis of the claims data to reflect our FY 2022 finalization, and also to determine to what extent the patient's co-morbid conditions are also contributing to costs and to identify other contributing factors that might exist with respect to the increased length of stay and costs of this subset of cases in these MS–DRGs, as discussed in the FY 2022 IPPS/LTCH PPS final rule.

Comment: Commenters expressed support of CMS' decision to allow additional time for the claims data to reflect our FY 2022 finalization before further analysis. Commenters stated that the finalized changes to surgical hierarchy for cardiac procedures were positive and will improve patient access. Other commenters stated that the finalized changes to the MS–DRG assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation were timely.

Response: We thank the commenters for their support.

Comment: Some commenters opposed CMS' decision and suggested that Medicare cover both aortic valve replacement surgery and surgical treatment for atrial fibrillation.

Response: We note that the Definitions Manual display of the GROUPER logic assignment for each procedure code is not an indication of whether or not a particular procedure is covered for payment purposes. The MS–DRG logic must specifically require a condition to group based on whether it is reported as a principal diagnosis or a secondary diagnosis, and consider any procedures that are reported, in addition to consideration of the patient's age, sex and discharge status in order to affect the MS–DRG assignment. In other words, cases will group according to the GROUPER logic, regardless of any coding guidelines or coverage policies. It is the Medicare Code Editor (MCE) and other payer-specific edits that identify inconsistencies in the coding guidelines or coverage policies. These data integrity edits address issues such as data validity, coding rules, and coverage policies. Since the inception of the IPPS, the data editing function has been a separate and independent step in the process of determining a DRG assignment. The separation of the MS–DRG grouping and data editing functions allows the MS–DRG GROUPER to remain stable even though coding rules and coverage policies may change during the fiscal year.

Comment: Other commenters opposed CMS' decision and stated CMS needs to finish the work that was started and improve hospital payment for valvular procedures with surgical ablation for atrial fibrillation. These commenters stated that the finalization of the revision to the surgical hierarchy for the MS–DRGs in MDC 05 and the finalization of the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS–DRGs 233 and 234 in FY 2022 rulemaking does not address the increased costs of cases describing open concomitant surgical ablation performed with open valve procedures that are assigned to MS–DRGs 216 through 221. A few commenters asserted that hospitals are forced to lose money on these lifesaving treatments because CMS has not addressed this underpayment. Other commenters stated that CMS did not provide transparent data analysis of cases describing open surgical ablation for atrial fibrillation performed during open valve procedures so the provider community could appropriately evaluate.

Commenters stated that treating atrial fibrillation during the same surgical session as an open valve procedure requires significant device costs, additional operating room time, and specialized staff. A commenter stated that even if the surgical ablation procedure is less technically complex than CABG, MVR, and/or AVR, hospitals still bear significant costs for furnishing the ablation procedure when the additional costs of the innovative device technologies (such as radiofrequency ablation clamps, cryoablation probes, and left atrial appendage management devices) that are used during the procedure are considered. Commenters expressed concern that given the added costs of performing as many as three procedures at the same time, hospitals may more likely schedule the patient for separate procedures even though guidelines of the Society for Thoracic Surgeons and the Heart Rhythm Society recommend performing surgical ablation for atrial fibrillation at the time of open-heart procedures when indicated. These commenters further stated they believed it did not seem financially prudent to compel patients to undergo multiple procedures, potentially costing more in the long run, when their atrial fibrillation could be treated during the same open-heart operation. Many commenters urged CMS to either (1) assign the cases to a different family of MS–DRGs or (2) assign these cases to MS–DRGs 216 and 217 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC and with CC, respectively) as originally requested.

Another commenter stated they respected the position of CMS' clinical advisors given the complexity of the involved procedures and noted that the issue of multiple procedures or interventions performed during a single hospital stay is also a problem in other areas of cardiology and warrants a meaningful solution. This commenter stated they believed that since performing procedures concomitantly is more efficient, more convenient, provides a better prognosis for the patient and could be more cost effective than the procedures being performed in different hospital stays, there should be a mechanism for differentiated payment when procedures are performed concomitantly, when it is best for the patient. This commenter recommended that CMS create a supplemental payment mechanism that could be modeled based on the respective costs of the individual procedures determined by claims data and then adjusted for efficiencies of a single operative session to facilitate incremental payment when two major procedures are performed during the same hospital admission and urged CMS to solicit further comment on possible methodological solutions to accommodate costs when two procedures are performed concomitantly.

Response: We appreciate the commenters' feedback.

We refer readers to Tables 6P.1c and 6P1.d associated with this final rule (which are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the data analysis of cases reporting procedure code combinations describing open concomitant surgical ablations in the September 2021 update of the FY 2021 MedPAR file. Table 6P.1c associated with this final rule sets forth the list of ICD–10–PCS procedure codes reflecting mitral valve repair or replacement (MVR), aortic valve repair or replacement (AVR), and coronary artery bypass grafting (CABG) procedures that we examined in this analysis. Table 6P.1d associated with this final rule shows the data analysis findings of cases reporting procedure code combinations describing open concomitant surgical ablations assigned to MS–DRGs 216, 217, 218, 219, 220 and

221 from the September 2021 update of the FY 2021 MedPAR file.

As shown in Table 6P.1d associated with this final rule, while the average lengths of stay and average costs of cases reporting procedure code combinations describing open concomitant surgical ablations are higher than all cases in their respective MS–DRG, we found there is variation in the volume, length of stay, and average costs of the cases. For MS–DRG 216, we found 870 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 16.8 days to 20.5 days and average costs ranging from $90,122 to $156,617 for these cases. For MS–DRG 217, we found 168 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 7.5 days to 12 days and average costs ranging from $48,644 to $74,594 for these cases. For MS–DRG 218, we found zero cases reporting procedure code combinations describing open concomitant surgical ablations. For MS–DRG 219, we found 1,940 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 11.2 days to 13.4 days and average costs ranging from $70,816 to $86,805 for these cases. For MS–DRG 220, we found 1,338 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 7.1 days to 8.8 days and average costs ranging from $49,326 to $65,611 for these cases. For MS–DRG 221, we found 60 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 5.6 days to 6.3 days and average costs ranging from $44,247 to $47,418 for these cases.

As noted, and similar to our analysis of the data for the FY 2022 IPPS/LTCH PPS rulemaking, the data analysis shows that while the average lengths of stay and average costs of cases reporting procedure code combinations describing open concomitant surgical ablations are higher than all cases in their respective MS–DRG, there is variation in the volume, length of stay, and average costs of the cases. As we discuss later in this section, the analysis also shows that the cases reporting an open concomitant surgical ablation code combination are predominately found in the higher (CC or MCC) severity level MS–DRGs of their current base MS–DRG assignment. Moreover, as also previously noted, the data from the September 2021 update of the FY 2021 MedPAR file does not reflect our FY 2022 finalization. We continue to believe that additional time is needed to allow for further analysis of the claims data to reflect our FY 2022 finalization, and also to determine to what extent the patient's co-morbid conditions or other factors may be contributing to the increased length of stay and costs of this subset of cases, as discussed previously.

In response to comments that urged CMS to assign cases reporting procedure code combinations describing open concomitant surgical ablations currently assigned to MS–DRGs 216, 217, 218, 219, 220 and 221 to MS–DRGs 216 and 217 only, MS–DRGs 216, 217 and 218 are defined by the performance of cardiac catheterization. The performance of a cardiac catherization procedure could be also contributing to the increased average costs of cases reporting procedure code combinations describing open concomitant surgical ablations currently assigned to MS–DRGs 216, 217 and 218. Our clinical advisors have expressed concern about the effect on clinical coherence of assigning cases reporting procedure code combinations describing open concomitant surgical ablations that do not also have a cardiac catherization procedure reported to MS–DRGs that are defined by the performance of that procedure.

We also note, as discussed in Section D.1.b of the proposed rule and this final rule, using the September 2021 update of the FY 2021 MedPAR file, we analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2022. Similar to our findings discussed in the FY 2022 IPPS/LTCH final rule, findings from our analysis using the September 2021 update of the FY 2021 MedPAR file indicated that MS–DRGs 216, 217, 218 as well as approximately 40 other MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. While we are finalizing the delay of the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split until FY 2024 or later, and to maintain the current structure of the 41 MS–DRGs that currently have a three-way severity level split (total of 123 MS–DRGs) that would otherwise be subject to these criteria, we note that the total number of cases in MS–DRG 218 is again below 500, and that we may consider consolidating these MS–DRGs into two severity levels based on the application of the NonCC subgroup criteria in future rule-making. We refer the reader to Table 6P.1b associated with the proposed rule and this final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of the 123 MS–DRGs that would be subject to deletion and the list of the 75 new MS–DRGs that would have been proposed for creation under this policy if the NonCC subgroup criteria were applied.

In response to comments that the finalized revision to the surgical hierarchy did not adequately address the increased costs of cases associated with open concomitant surgical ablation and that urged CMS to create new MS–DRGs for these open concomitant procedures as originally requested, our clinical advisors continue to believe additional time is needed to review the clinical nature of cases reporting an open concomitant surgical ablation code combination before exploring a proposal to create new MS–DRGs for this subset of cases currently assigned to MS–DRGs 216 through 221 given the complexity of these code combinations and the corresponding data. Our analysis using the September 2021 update of the FY 2021 MedPAR file reflects that the cases reporting an open concomitant surgical ablation code combination are predominately found in the higher (CC or MCC) severity level MS–DRGs of their current base MS–DRG assignment, suggesting that the patient's co-morbid conditions may also be contributing to higher costs of these cases. Secondly, for the numerous procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure, the increase in average costs appears to directly correlate with the number of procedures performed. For example, cases that describe ''Open MVR + open surgical ablation'' generally demonstrate costs that are lower than cases that describe ''Open MVR + open AVR + open CABG + open surgical ablation.'' Therefore, our clinical advisors continue to believe that additional time is needed to allow for further analysis of the claims data to determine to what extent the patient's co-morbid conditions are also contributing to higher costs and to identify other contributing factors that might exist with respect to the increased length of stay and costs of these cases in these MS–DRGs. Our clinical advisors continue to believe that future data findings may demonstrate additional variance in resource utilization for this patient population.

With respect to commenters' concerns regarding a mechanism for

differentiated payment when procedures are performed concomitantly, we agree that the performance of concomitant procedures is an area that warrants more analysis across the MS–DRG classification, as the performance of ''concomitant procedures'' may affect the consumption of resources in other clinical scenarios as well, especially when the use of devices is involved. As discussed in prior rulemaking, the MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. It has been difficult to identify other MS–DRGs that would be more appropriate MS–DRG assignments for these concomitant procedures based on the variance in the clinical characteristics and utilization of resources for concomitant procedures, which can depend on the number of procedures being performed concomitantly and the nature of these procedures. We are interested in receiving feedback on possible mechanisms through which we can address concomitant procedures. We are also interested in receiving feedback on how CMS can mitigate any unintended negative payment impacts to providers providing concomitant procedures. Commenters can continue to submit their recommendations via the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home*. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

Comment: Some commenters noted that cases describing standalone hybrid percutaneous endoscopic surgical ablation are assigned MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) and noted that payment for MS–DRGs 228 and 229 has been trending downward over the last six years. These commenters stated that the downward payment trend for MS–DRGs 228 and 229 has resulted in hospitals being undercompensated for the costs of furnishing standalone hybrid percutaneous endoscopic surgical ablation procedures for atrial fibrillation. Other commenters stated that CMS did not provide transparency to the details of its analysis to support why standalone hybrid surgical ablation procedures should not be moved from MS–DRGs 228 and 229.

Some commenters stated that the decline in payment for standalone hybrid percutaneous endoscopic surgical ablation procedures makes it impossible for their facilities to continue to provide these needed procedures to patients suffering from atrial fibrillation. A commenter stated the proposed relative weight does not accurately reflect the costs of these device intensive procedures and that there has been no transparency into the cause for these significant declines. Another commenter stated that their facility has been especially impacted by COVID–19 and stated that for CMS to expect facilities to be able to continue to provide patients with needed medical services such as hybrid percutaneous endoscopic surgical ablation at such a steep decrease in payment is intolerable for hospitals. Other commenters asserted that hospitals will be forced to postpone or ''trim back'' on providing patients access to more complex, resource intensive procedures such as these, to better align their costs with what they asserted were Medicare's inadequate payment levels. These commenters proposed two possible remedies to this underpayment, that CMS either (1) use its statutory authority to not reduce the relative weight and payment for MS–DRGs 228 and 229, or (2) assign cases reporting procedure codes describing standalone percutaneous endoscopic surgical ablation from MS–DRGs 228 and 229 to the higher (MCC) severity level MS–DRG of its current base MS–DRG assignment, which is MS–DRG 228 (Other Cardiothoracic Procedures with MCC), to prevent underpayment for these procedures and avoid disruptions in beneficiary access.

Response: We appreciate the commenters' feedback. We note that we did not receive a specific request to change the MS–DRG assignment for standalone percutaneous endoscopic surgical ablation procedures for consideration for the FY 2023 IPPS/LTCH PPS proposed rule. We note a request to reassign cases describing standalone percutaneous endoscopic surgical ablation from MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) to higher weighted MS–DRGs 219 and 220 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC and with CC, respectively) was discussed in the FY 2022 IPPS/LTCH PPS proposed rule. In the FY 2022 IPPS/LTCH final rule, in response to comments received on the proposed rule, we also discussed the assignment of cases reporting procedure codes describing standalone percutaneous endoscopic surgical ablation from MS–DRGs 228 and 229 to the higher (MCC) severity level MS–DRG of its current base MS–DRG assignment in the FY 2022 IPPS/LTCH PPS final rule. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44844 through 44848) for a complete discussion.

In the request to again review the MS–DRG assignment of surgical ablation procedures in FY 2023 rulemaking, however, the requestor stated in their submission that while surgical ablation represents losses across all procedure types, they recommended focusing on addressing open concomitant surgical ablation in FY 2023 rulemaking and did not request a change to the MS–DRG assignment for standalone percutaneous endoscopic surgical ablation. Therefore, cases describing standalone percutaneous endoscopic surgical ablation were not considered in the FY 2023 IPPS/LTCH PPS proposed rule.

In response to the comment that hospitals may postpone or ''trim back'' on providing patients access to these procedures in order to better align their costs with Medicare payment levels, as we have stated in prior rulemaking, it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that potentially involves increased costs.

We acknowledge the reduction in the proposed FY 2023 relative weights for MS–DRGs 228 and 229 (approximately 7% and 4%, respectively from the FY 2022 relative weight), however, we note we did not propose a change to the GROUPER logic of MS–DRGs 228 and 229 for FY 2023. However, there have been previous changes to the structure of MS–DRGs 228 and 229 over the past six years. It is to be expected that when MS–DRGs are restructured, such as when procedure codes are reassigned or the hierarchy within an MDC is revised, resulting in a different case-mix within the MS–DRGs, the relative weights of the MS–DRGs will change as a result. We believe the trending reduction in relative weights for MS–DRGs 228 and 229 over time to be appropriately driven by the underlying data in the six years since CMS began using the ICD–10 data in calculating the relative weights and is reflective of the change in case-mix within these MS–DRGs. Specifically, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56809 through 56813), we finalized our proposal to collapse MS–DRGs 228, 229, and 230 from three severity levels to two severity levels by deleting MS–DRG 230 and revised the structure of MS- DRG 229. We also finalized our proposal to reassign ICD–9–CM procedure code 35.97 and the cases reporting ICD–10–PCS procedure

code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) from MS–DRGs 273 and 274 to MS–DRG 228 and revised the titles of MS–DRG 228 and 229. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42080 through 56813) we finalized our proposal to modify the structure of MS–DRGs 266 and 267 by reassigning ICD–10–PCS procedure code 02UG3JZ describing a transcatheter mitral valve repair with implant procedure from MS–DRGs 228 and 229 to MS–DRGs 266 and 267 and revised the titles of MS–DRGs 266 and 267. Finally, as discussed in the FY 2022 IPPS/LTCH PPS final rule, and earlier in this section, we finalized a revision to the surgical hierarchy for the MS–DRGs in MDC 05 to sequence MS–DRGs 231–236 (Coronary Bypass) above MS–DRGs 228 and 229 for FY 2022. Therefore, the data appear to reflect that the difference in the relative weights shown in Table 5–List of Medicare Severity Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay associated with final rule for the applicable fiscal year can be attributed to the fact that these previously finalized policies resulted in a different case-mix within the MS–DRGs, which is then being reflected in the relative weights. We refer the reader to section II.E. of the preamble of this FY 2023 IPPS/LTCH PPS final rule for a complete discussion of the relative weight calculations for FY 2023, including our finalized policies to use 50 percent of the relative weights calculated using all cases in the FY 2021 MedPAR data and 50 percent of the relative weights calculated without COVID–19 cases in the FY 2021 MedPAR data to calculate the relative weights for FY 2023, and to apply a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, beginning in FY 2023.

We appreciate the commenters' support and feedback, and intend to continue to consider these issues. For the reasons summarized earlier, and after consideration of the public comments we received, we are not making any MS–DRG changes for cases involving the open concomitant surgical ablation procedures or for cases describing standalone percutaneous endoscopic surgical ablation for FY 2023.

7. MDC 06 (Diseases and Disorders of the Digestive System): Appendicitis

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28163 through 28165), we discussed a request we received to reconsider the MS–DRG assignment for diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess). According to the requestor, when this code is reported in combination with any one of the corresponding procedure codes that describe an appendectomy, the case is grouping to MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). Alternatively, the requestor stated that when diagnosis code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) is reported in combination with any one of the corresponding procedure codes that describe an appendectomy, the case is grouping to MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

The requestor asserted that the difference in MS–DRG assignment suggests that localized peritonitis is more severe or requires an additional level of care over and above that for generalized peritonitis. The requestor stated that clinically, both localized and generalized peritonitis, when treated with an appendectomy require the same level of patient care, including extensive intraoperative irrigation at the surgical site, direct inspection or imaging of the abdomen to look for possible abscess, use of intravenous antibiotics, and prolonged inpatient monitoring. The requestor added that generalized peritonitis can be thought of as a progression of the localized peritonitis condition and that patients progress from localized to generalized peritonitis and not vice versa.

In the proposed rule we noted that this topic has been discussed previously in our FY 2019 (83 FR 41230) and FY 2021 rulemakings (85 FR 32500 through 32503) and (85 FR 58484 through 58488). Effective FY 2019 (October 1, 2018) diagnosis code K35.2 (Acute appendicitis with generalized peritonitis) was expanded to K35.20 (Acute appendicitis with generalized peritonitis, without abscess); and K35.21 (Acute appendicitis with generalized peritonitis, with abscess). In addition, code K35.3 (Acute appendicitis with localized peritonitis) was expanded to K35.30 (Acute appendicitis with localized peritonitis, without perforation or gangrene); K35.31 (Acute appendicitis with localized peritonitis and gangrene, without perforation); K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess); and K35.33 (Acute appendicitis with perforation and localized peritonitis, with abscess).

We finalized the severity level designations for these new diagnosis codes in the FY 2019 IPPS/LTCH PPS final rule and stated our clinical advisors believed that the new diagnosis codes for acute appendicitis described as ''with abscess'' or ''with perforation'' were clinically qualified for the MCC severity level designation, while acute appendicitis ''without abscess'' or ''without perforation'' were clinically qualified for the CC severity level designation because cases with abscess or perforation would be expected to require more clinical resources and time to treat while those cases ''without abscess'' or ''without perforation'' are not as severe clinical conditions.

As discussed in our FY 2021 rulemaking, we received the request to add K35.20 (Acute appendicitis with generalized peritonitis, without abscess) to the list of complicated principal diagnoses so that all ruptured/perforated appendicitis codes in MDC 06 group to MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) as K35.20 is the only ruptured appendicitis code not included in the list of complicated principal diagnosis codes. At that time, we noted that the inclusion term at subcategory K35.2 (Acute appendicitis with generalized peritonitis) is: ''Appendicitis (acute) with generalized (diffuse) peritonitis following rupture or perforation of the appendix''. The requestor stated that code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) describes a generalized, more extensive form of peritonitis than code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess). We noted that our clinical advisors agreed that the presence of an abscess would clinically determine whether a diagnosis of acute appendicitis would be considered a complicated principal diagnosis. As diagnosis code K35.20 is described as ''without'' an abscess, our clinical advisors recommended that K35.20 not be added to the list of complicated principal diagnoses for MS–DRGS 338, 339, and 340. We also proposed to remove diagnosis code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) from the complicated principal diagnosis list.

In response to that proposal, some commenters disagreed. A commenter stated that when ruptured appendicitis results in generalized peritonitis, resources are greater because the

infection is not walled off, not localized, and has spread to two or more compartments within the abdominal cavity. According to the commenter, clinical literature supports the statement that generalized peritonitis is a more morbid (severe) presentation than just perforation or localized abscess. After consideration of the comments received and for the reasons discussed in the FY 2021 final rule, we did not finalize our proposals in that final rule. We concurred that the expansion of diagnosis codes K35.2 and K35.3 to introduce additional clinical concepts effective October 1, 2018 significantly changed the scope and complexity of the diagnosis codes for this subset of patients. We also stated NCHS' staff acknowledged the clinical concerns based on the manner in which diagnosis codes K35.2 and K35.3 were expanded and confirmed that they would consider further review of these newly expanded codes with respect to the clinical concepts.

We communicated with the CDC/NCHS staff regarding this repeat request submitted for FY 2023 consideration. The CDC/NCHS staff included these codes describing appendicitis on the agenda and a proposal for further revisions was presented for discussion at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting. Specifically, the CDC/NCHS staff proposed to expand current diagnosis codes K35.20 and K35.21, making them sub-subcategories and creating new diagnosis codes to identify and describe acute appendicitis with generalized peritonitis, with perforation and without perforation, and unspecified as to perforation, as shown in the following table.

Proposed ICD-10-CM Code	Description
K35.200	Acute appendicitis with generalized peritonitis, without perforation or abscess
K35.201	Acute appendicitis with generalized peritonitis, with perforation, without abscess
K35.209	Acute appendicitis with generalized peritonitis, without abscess, unspecified as to perforation
K35.210	Acute appendicitis with generalized peritonitis, without perforation, with abscess
K35.211	Acute appendicitis with generalized peritonitis, with perforation and abscess
K35.219	Acute appendicitis with generalized peritonitis, with abscess, unspecified as to perforation

We refer the reader to the CDC website at: *https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm* for additional detailed information regarding the proposal, including a recording of the discussion and the related meeting materials.

We noted in the proposed rule that the deadline for submitting public comments on the diagnosis code proposals discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting was May 9, 2022 and according to the CDC/NCHS staff, the diagnosis code proposals are being considered for an October 1, 2023 implementation (FY 2024). We stated that any future proposed changes to the MS–DRGs for Appendectomy would be dependent on the diagnosis code revisions that are finalized by the CDC/NCHS. Since it is not clear what code changes may be finalized, including whether public comments expressed support for the proposed changes or provided alternative options for consideration, we stated in the proposed rule that we believe it is appropriate to delay any possible MS–DRG modifications for future rulemaking. Therefore, we did not propose a change to the MS–DRG assignment or the current structure for MS–DRGs 338, 339, 340, 341, 342, and 343. Although we did not propose a change to the MS–DRG assignments for FY 2023, we made the findings from our data analysis available for the listed MS–DRGs and the associated diagnosis codes to help inform future comments. We referred the reader to Table 6P.4a associated with the proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*).

Comment: Commenters agreed with our proposal to maintain the structure of MS–DRGs 338, 339, 340, 341, 342, and 343 including the MS–DRG assignment for diagnosis code K35.20 to MS–DRGs 341, 342, and 343. However, a commenter opposed CMS's proposal and stated they agreed with the requestor that all diagnosis codes describing a ruptured or perforated appendix should group to MS–DRGs 338, 339, and 340. The commenter stated that the condition described by code K35.20 can be associated with the risk of postoperative abscess formation and extended length of hospital stay, thereby warranting classification as a complicated diagnosis. This commenter urged CMS to reassign code K35.20 from MS–DRGs 341, 342, and 343 to MS–DRGs 338, 339, and 340 for FY 2023.

Response: We thank the commenters for their support and feedback. In response to the commenter who urged CMS to reassign diagnosis code K35.20 from MS–DRGs 341, 342, and 343 to MS–DRGs 338, 339, and 340 for FY 2023, we note that the CDC/NCHS staff are in the process of reviewing public comments related to the proposed revision to certain diagnosis codes describing acute appendicitis that was presented at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting, as discussed in the proposed rule. Accordingly, we continue to believe it is appropriate to delay any potential MS–DRG modifications as we do not yet know what the finalized code updates, including any corresponding changes to the Index to Diseases and Injuries and Tabular List of Diseases, might be. We will continue to collaborate with the CDC/NCHS regarding this issue.

After consideration of the public comments we received, we are maintaining the current structure of MS–DRGs 338, 339, 340, 341, 342, and 343 and the MS–DRG assignment of diagnosis code K35.20 for FY 2023.

8. MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas): Laparoscopic Cholecystectomy With Common Bile Duct Exploration

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28165), we stated that we received a request to review the MS–DRG assignment when procedure code 0FC94ZZ (Extirpation of matter from common bile duct, percutaneous endoscopic approach) that describes a common bile duct exploration with gallstone removal procedure using a laparoscopic approach, is reported with a laparoscopic cholecystectomy. The procedure codes describing a laparoscopic cholecystectomy are

ICD-10-PCS Code	Description
0F544ZZ	Destruction of gallbladder, percutaneous endoscopic approach
0F548ZZ	Destruction of gallbladder, via natural or artificial opening endoscopic
0FB44ZZ	Excision of gallbladder, percutaneous endoscopic approach
0FB48ZZ	Excision of gallbladder, via natural or artificial opening endoscopic
0FT44ZZ	Resection of gallbladder, percutaneous endoscopic approach

According to the requestor, when a laparoscopic cholecystectomy is reported with any one of the listed procedure codes with a common bile duct exploration and gallstone removal procedure that is performed laparoscopically and reported with procedure code 0FC94ZZ, the resulting assignment is MS–DRGs 417, 418 and 419 (Laparoscopic Cholecystectomy without C.D.E. with MCC, with CC, and without CC/MCC, respectively). This MS–DRG assignment does not recognize that a common bile duct exploration (C.D.E.) was performed. However, the requestor stated that when procedure code 0FC90ZZ (Extirpation of matter from common bile duct, open approach) that describes a common bile duct exploration with gallstone removal procedure using an open approach is reported with any one of the listed procedure codes describing a laparoscopic cholecystectomy, the resulting assignment is MS–DRGs 411, 412, and 413 (Cholecystectomy with C.D.E. with MCC, with CC, and without CC/MCC, respectively). The requestor stated that this MS–DRG assignment appropriately recognizes that a common bile duct exploration was performed. The requestor questioned why only the common bile duct exploration with gallstone removal procedure performed using an open approach (code 0FC90ZZ) grouped appropriately when reported with the laparoscopic cholecystectomy.

We stated in the proposed rule that we reviewed procedure code 0FC94ZZ and found that it is currently designated as a non-O.R. procedure, therefore, the GROUPER logic does not recognize this procedure for purposes of MS–DRG assignment. We also noted that MS–DRGs 411, 412, and 413 include cholecystectomy procedures performed by either an open or a percutaneous endoscopic (laparoscopic) approach. We referred the reader to the V39.1 ICD–10 MS–DRG Definitions Manual, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 411, 412, 413, 417, 418 and 419.

As stated in the proposed rule, we analyzed claims data from the September 2021 update of the FY 2021 MedPAR file for all cases in MS–DRGs 411, 412, 413, 417, 418, and 419. Because the logic for MS–DRGs 411, 412, and 413 includes cholecystectomy procedures performed by either an open or percutaneous endoscopic (laparoscopic) approach, we also analyzed the cases reported with each approach separately. The findings from our analysis are shown in the following tables.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
411	116	8.5	$29,332
412	152	6.8	$21,042
413	76	3.6	$12,427
417	10,448	6.3	$19,384
418	17,336	4.1	$13,627
419	9,479	2.7	$10,728

Number of Cases Reporting Open Cholecystectomy in MS-DRGs 411-413			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
411	56	10.73	$36,135
412	82	7.61	$23,390
413	28	4.3	$12,969
Total	**166**	**8.1**	**$25,932**

Number of Cases Reporting Laparoscopic Cholecystectomy in MS-DRGs 411-413			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
411	60	6.5	$22,982
412	70	5.8	$18,293
413	48	3.1	$12,110
Total	**178**	**5.3**	**$18,206**

In MS–DRG 411, we found a total of 116 cases with an average length of stay of 8.5 days and average costs of $29,332. Of those 116 cases, there were 56 cases reporting an open cholecystectomy, with an average length of stay of 10.7 days and average costs of $36,135 and 60 cases reporting a laparoscopic cholecystectomy, with an average length of stay of 6.5 days and average costs of $22,982. The data show that the cases reporting an open cholecystectomy have a longer average length of stay (10.7 days versus 6.5 days) and higher average costs ($36,135 versus $22,982) compared to the cases reporting a laparoscopic cholecystectomy. The data also show that the cases reporting an open cholecystectomy have a longer average length of stay (10.7 days versus 8.5 days) and higher average costs ($36,135 versus $29,332) compared to all the cases in MS–DRG 411. Similar findings are demonstrated for MS–DRGs 412 and 413, where the data show that the cases reporting an open cholecystectomy have a longer average length of stay and higher average costs compared to the cases reporting a laparoscopic cholecystectomy, and also, when compared to all the cases in their respective MS–DRGs.

We then analyzed claims data from the September 2021 update of the FY 2021 MedPAR file for cases reporting procedure code 0FC94ZZ in MS–DRGs 417, 418, and 419 to assess how often it was reported. The findings from our analysis are shown in the following table.

Number of Cases Reporting Procedure Code 0FC94ZZ in MS-DRGs 417-419			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
417	70	6.3	$17,685
418	96	4.4	$14,615
419	65	3.2	$13,914
Total	**231**	**4.6**	**$15,348**

We found a total of 231 cases across MS–DRGs 417, 418, and 419 with an average length of stay of 4.6 days and average costs of $15,348 reporting procedure code 0FC94ZZ. In our review of the cases reporting a laparoscopic cholecystectomy across MS–DRGs 411, 412, and 413, we found a total of 178 cases with an average length of stay of 5.3 days and average costs of $18,206.

We also examined claims data from the September 2021 update of the FY 2021 MedPAR file for cases reporting procedure code 0FC94ZZ across all the MS–DRGs without another O.R. procedure reported, to assess the number of cases and in which MS–DRGs procedure code 0FC94ZZ was found. The findings from our analysis are shown in the following table.

Number of Cases Reporting Procedure Code 0FC94ZZ without another O.R. Procedure Across All MS-DRGs			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
438 - Disorders of Pancreas Except Malignancy with MCC	2	14	$26,092
441 - Disorders of Liver Except Malignancy Cirrhosis or Alcoholic Hepatitis with MCC	1	16	$30,076
444 - Disorders of the Biliary Tract with MCC	6	5.2	$10,237
445 - Disorders of the Biliary Tract with CC	11	4	$14,015
446 - Disorders of the Biliary Tract without CC/MCC	5	2.6	$15,036
871 - Septicemia or Severe Sepsis without MV >96 Hours with MCC	6	8.8	$22,737
872 - Septicemia or Severe Sepsis without MV >96 Hours without MCC	1	3	$5,322
Total	**32**	**5.9**	**$16,087**

The data analysis shows procedure code 0FC94ZZ was reported in a total of 32 cases across 7 MS–DRGs with an average length of stay of 5.9 days and average costs of $16,087. While procedure code 0FC94ZZ is designated as non-O.R., we also analyzed the average length of stay and average costs of the cases found within each of the 7 MS–DRGs reporting procedure code 0FC94ZZ against all the cases in their respective MS–DRGs, to determine if there was any indication that the performance of the procedure described by procedure code 0FC94ZZ may have had any impact. For instance, as shown in the table, for MS–DRG 438 we found 2 cases reporting procedure code 0FC94ZZ with an average length of stay of 14 days and average costs of $26,092. In the September 2021 update of the FY 2021 MedPAR file, the total number of cases for MS–DRG 438 is 10,240 with an average length of stay of 6.4 days and average costs of $13,341. The 2 cases reporting procedure code 0FC94ZZ have approximately twice the average length of stay (14 days versus 6.4 days) and approximately twice the average costs ($26,092 versus $13,341) compared to all the cases for MS–DRG 438. In the absence of additional analysis, it is unknown if these differences can be attributed to other factors, such as the MCCs that were reported in these cases. Similar findings were found for MS–DRGs 441, 445, 446, and 871. We noted in the proposed rule that we will consider if further detailed analysis may be warranted for these cases.

As stated in the proposed rule, our clinical advisors agreed that procedure code 0FC94ZZ describes a common bile duct exploration procedure with removal of a gallstone and should be added to the logic for case assignment to MS–DRGs 411, 412, and 413 for clinical coherence with the other procedures that describe a common bile duct exploration. Therefore, for FY 2023, we proposed to redesignate procedure code 0FC94ZZ from a non-O.R. procedure to an O.R. procedure and add it to the logic list for common bile duct exploration (CDE) in MS–DRGs 411, 412, and 413 (Cholecystectomy with C.D.E. with MCC, with CC, and without CC/MCC, respectively) in MDC 07 to appropriately reflect when this procedure is performed and improve the clinical coherence of the patients assigned to these MS–DRGs.

Comment: Commenters agreed with our proposal to redesignate procedure code 0FC94ZZ from a non-O.R. procedure to an O.R. procedure and to add it to the logic list for common bile duct exploration (CDE) procedures in MS–DRGs 411, 412, and 413.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to redesignate procedure code 0FC94ZZ from a non-O.R. procedure to an O.R. procedure and to add it to the logic list for common bile duct exploration (CDE) procedures in MS–DRGs 411, 412, and 413 for FY 2023.

In addition, we noted in the proposed rule that MS–DRGs 414, 415, and 416 (Cholecystectomy Except by Laparoscope without C.D.E. with MCC, with CC and without CC/MCC, respectively) also reflect cholecystectomy procedures, however, the logic is specifically defined for open cholecystectomy procedures *without* a common bile duct exploration procedure performed. Since MS–DRGs 411, 412, and 413 reflect cases where an open or laparoscopic cholecystectomy is performed *with* a common bile duct exploration procedure, MS–DRGs 414, 415, and 416 reflect cases where only an open cholecystectomy is performed *without* a common bile duct exploration procedure, and MS–DRGs 417, 418, and 419 reflect cases where only a laparoscopic cholecystectomy is performed *without* a common bile duct exploration procedure, we stated we believe there may be an opportunity to further refine these MS–DRGs once additional analysis is performed for consideration in future rulemaking. For example, we indicated we could consider proposing to restructure these cholecystectomy MS–DRGs to reflect the following two concepts, if supported by the data, and relatedly, to determine if severity levels are also supported according to the existing criteria.

- Open Cholecystectomy with or without C.D.E.; and
- Laparoscopic Cholecystectomy with or without C.D.E.

Comment: Commenters agreed that there may be an opportunity to further refine the MS–DRGs for cholecystectomy procedures and encouraged CMS to conduct further review and analysis of the procedure codes describing cholecystectomy with common bile duct exploration for consideration in future rulemaking.

Response: We thank the commenters for their support and continue to solicit any additional feedback from the public on this and any alternative recommendations or options to further refine these MS–DRGs for future consideration. As discussed in section II.D.1.b. of the preamble of the proposed rule and this final rule, feedback and other suggestions should be directed to the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home*, with any comments and suggestions for consideration for FY 2024 to be submitted by October 20, 2022.

9. MDC 10 (Diseases and Disorders of the Endocrine System): Eladocagene Exuparvovec Gene Therapy

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44895), we finalized the redesignation of code XW0Q316 (Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6) from a Non-O.R. procedure to an O.R. procedure, assigned to MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively). In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28167 through 28168) we discussed a request we received to reconsider this assignment for FY 2023. According to the requestor, the clinical characteristics and costs of cases assigned to MS–DRGs 628 through 630 are significantly different from those associated with the administration of eladocagene exuparvovec. The requestor performed its own analysis, using deep brain stimulation for epilepsy and selective dorsal rhizotomy for cerebral palsy as proxies, and stated that based on its findings for the initial cost analysis and clinical comparison, that MS–DRG 23 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator), MS–DRG 24 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC) and MS–DRGs 25, 26, and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively) may be more appropriate. However, the requestor also stated that while the clinical aspects of eladocagene exuparvovec cases are similar to those of MS–DRGs 23 through 27, the costs are much higher and neither MS–DRGs 628, 629, 630 or MS–DRGs 23 through 27 are appropriate. Therefore, the requestor stated its belief

that assigning eladocagene exuparvovec cases to new MS–DRGs is warranted.

Eladocagene exuparvovec is a gene therapy for the treatment of patients with aromatic L-amino acid decarboxylase (AADC) deficiency, a rare genetic and fatal condition identified with ICD–10–CM diagnosis code E70.81. Patients with AADC deficiency are generally observed to have onset of symptoms in the first year of life, most notably hypotonia (muscle weakness), followed by movement disorders, developmental delay and autonomic signs, such as hyperhidrosis (profuse sweating unrelated to heat or exercise). It is understood that the long-term implications of this disease are severe, resulting in severe deficits and limitations in life expectancy. Because the condition is primarily diagnosed in the pediatric population, we would not expect to find any meaningful volume of cases in the MedPAR data.

As discussed in the proposed rule, we analyzed claims data from the September 2021 update of the FY 2021 MedPAR file for MS–DRGs 628, 629, and 630 for cases reporting procedure code XW0Q316 and did not find any cases. We then extended our analysis to all MS–DRGs and found 1 case reporting the administration of this therapy in MS–DRG 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with CC/MCC) with an average length of stay of 2 days and average costs of $1,544. As we have discussed elsewhere we generally prefer not to create a new MS–DRG unless it would include a substantial number of cases. However, as discussed in section II.D.19.b. of the preamble of the proposed rule and this final rule, we are seeking public comment on possible mechanisms through which we can address rare diseases and conditions that are represented by low volumes in our claims data. We believe this topic, relating to the administration of treatment to address the rare genetic and fatal condition of AADC deficiency, is appropriately aligned with and should be considered as part of that effort. Therefore, we stated in the proposed rule that we are maintaining the current structure for MS–DRGs 628, 629, and 630 for FY 2023, but would continue to consider this request in connection with our evaluation of possible mechanisms to address rare diseases and conditions in the MS–DRG structure, as discussed later in this rule.

Comment: Commenters agreed with our decision to maintain the current MS–DRG assignment for cases reporting the administration of eladocagene exuparvovec. Other commenters urged CMS to consider appropriate MS–DRG assignment and payment for gene therapy intracerebral infusion therapies. The commenters stated there is anticipated rapid development and potential for these therapies to help patients. The commenters also expressed appreciation for CMS' request for feedback on MS–DRG assignment for rare diseases and stated that gene therapy represents an area of significant innovation in treating these conditions. The commenters suggested that CMS carefully consider the MS–DRG assignment for procedures that involve an intracerebral infusion of gene therapy or stem cell products that are currently under development for several neurologic disorders including Parkinson's, which is very common, and aromatic L-amino acid decarboxylase deficiency, which is very rare. The commenters stated that intracerebral infusion therapies are unique procedures requiring vastly different hospital resources compared to more traditional neurosurgical procedures. According to the commenters, appropriate MS–DRG assignment or consideration for creating new MS–DRG categories will be essential to assuring access to these therapies.

Response: We appreciate the commenters' support and feedback.

Comment: A couple commenters disagreed with CMS's decision to maintain the current MS–DRG assignment for cases reporting the administration of eladocagene exuparvovec. The commenters requested that CMS consider creating a new MS–DRG for neurosurgical gene therapy. A commenter indicated that because eladocagene exuparvovec has not yet been approved by the FDA they are unable to appropriately identify cases in the claims data. This commenter stated that there are currently approximately 68 gene therapy trials for central nervous system disorders, therefore, the decision to create or not create a new MS–DRG may have broader implications.

Response: We appreciate the commenters' feedback. As discussed in the proposed rule, our analysis of claims data, which identified only one case reporting the administration of this therapy, did not support a proposal to create a new MS–DRG. The MS–DRGs are a classification system intended to group together those diagnoses and procedures with similar clinical characteristics and utilization of resources. As discussed previously and in prior rulemaking, we generally prefer not to create a new MS–DRG unless it would include a substantial number of cases, as having large clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights. We acknowledge the complexities related to classifying cases that are represented by low volumes in our claims data and believe that further review of this issue also aligns with our intent to consider how rare diseases or conditions may be classified under the IPPS.

After consideration of the public comments we received, we are maintaining the current MS–DRG assignment for cases reporting the administration of eladocagene exuparvovec for FY 2023. We will continue to explore appropriate mechanisms to address therapies indicated for rare diseases. We also refer the reader to section II.D.19.a of the preamble of this final rule for a discussion of the feedback received in response to the comment solicitation on possible mechanisms to address rare diseases and conditions in the MS–DRG structure.

10. MDC 15 Newborns and Other Neonates With Conditions Originating in Perinatal Period: MS–DRG 795 Normal Newborn

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28168 through 28170), we discussed a request we received to review the MS–DRG assignment of newborn encounters with diagnosis codes describing contact with and (suspected) exposure to COVID–19 when the condition is ruled out after clinical evaluation and negative workup. The requestor expressed concern that a newborn encounter coded with a principal diagnosis code from category Z38 (Liveborn infants according to place of birth and type of delivery), followed by codes Z05.1 (Observation and evaluation of newborn for suspected infectious condition ruled out) and Z20.822 (Contact with and (suspected) exposure to COVID–19) is assigned to MS–DRG 794 (Neonate with Other Significant Problems). The requestor stated that this assignment appears to be in error and that the assignment should instead be to MS–DRG 795 (Normal Newborn).

In the proposed rule we stated that our analysis of this grouping issue confirmed that, when a principal diagnosis code from category Z38 (Liveborn infants according to place of birth and type of delivery), followed by codes Z05.1 (Observation and evaluation of newborn for suspected infectious condition ruled out) and Z20.822 (Contact with and (suspected) exposure to COVID–19), the case is assigned to MS–DRG 794.

We stated that as we examined the GROUPER logic that would determine an assignment of cases to MS–DRG 795, we noted the ''only secondary diagnosis'' list under MS–DRG 795 includes the following five ICD–10–CM diagnosis codes from ICD–10–CM category Z20. We refer the reader to the ICD–10 MS–DRG Version 39.1 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for the MS–DRG 795.

ICD-10-CM Code	Description
Z20.09	Contact with and (suspected) exposure to other intestinal infectious diseases
Z20.7	Contact with and (suspected) exposure to pediculosis, acariasis and other infestations
Z20.810	Contact with and (suspected) exposure to anthrax
Z20.818	Contact with and (suspected) exposure to other bacterial communicable diseases
Z20.89	Contact with and (suspected) exposure to other communicable diseases

As discussed in the proposed rule, in reviewing the ICD–10–CM diagnosis code classification and the GROUPER logic list, we noted that the 13 ICD–10–CM diagnosis codes, also from category Z20, listed in the following table were inadvertently omitted from the ''only secondary diagnosis'' list under MS–DRG 795.

ICD-10-CM Code	Description
Z20.01	Contact with and (suspected) exposure to intestinal infectious diseases due to Escherichia coli (E. coli)
Z20.1	Contact with and (suspected) exposure to tuberculosis
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z20.3	Contact with and (suspected) exposure to rabies
Z20.4	Contact with and (suspected) exposure to rubella
Z20.5	Contact with and (suspected) exposure to viral hepatitis
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
Z20.811	Contact with and (suspected) exposure to meningococcus
Z20.820	Contact with and (suspected) exposure to varicella
Z20.821	Contact with and (suspected) exposure to Zika virus
Z20.822	Contact with and (suspected) exposure to COVID-19
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
Z20.9	Contact with and (suspected) exposure to unspecified communicable disease

We reviewed section I.C.21.c.1 of the 2022 ICD–10–CM Official Guidelines for Coding and Reporting which state ''category Z20 indicates contact with, and suspected exposure to, communicable diseases. These codes are for patients who are suspected to have been exposed to a disease by close personal contact with an infected individual or are in an area where a disease is epidemic . . . Contact/exposure codes may be used as a first-listed code to explain an encounter for testing, or, more commonly, as a secondary code to identify a potential risk.'' Per the Excludes1 note at category Z20, when applicable, diagnoses of current infectious or parasitic disease are coded instead of codes from category Z20.

We stated in the proposed rule that our clinical advisors reviewed this issue and agreed that patients exposed to communicable diseases that are worked up or treated prophylactically or both, and for whom those conditions are later determined after study to not be present, are distinct from patients with identified signs or symptoms of a suspected problem or diagnosed with having that communicable disease. Our clinical advisors supported adding the 13 diagnosis codes listed previously to the logic of MS–DRG 795 for clinical consistency with the five other diagnosis codes describing contact with, and suspected exposure to, communicable diseases currently assigned to the ''only secondary diagnosis'' list under MS–DRG 795.

After review of the coding guidelines and conventions, and discussion with our clinical advisors, we stated that we agreed with the requestor that in these circumstances, these encounters should not map to MS–DRG 794 (Neonate with Other Significant Problems) and should instead be assigned to MS–DRG 795 (Normal Newborn). Therefore, we proposed to add the 13 diagnosis codes listed previously that describe contact with and (suspected) exposure to communicable diseases to the ''only secondary diagnosis'' list under MS–DRG 795 (Normal Newborn). Under this proposal, cases with a principal diagnosis described by an ICD–10–CM code from category Z38 (Liveborn infants according to place of birth and type of delivery), following by codes Z05.1 (Observation and evaluation of newborn for suspected infectious condition ruled out) and Z20.822 (Contact with and (suspected) exposure to COVID–19) will be assigned to MS–DRG 795.

Comment: Commenters expressed support for CMS' proposal to add the 13 diagnosis codes listed previously that describe contact with and (suspected) exposure to communicable diseases to the ''only secondary diagnosis'' list under MS–DRG 795 (Normal Newborn).

Response: We appreciate the commenters' support.

Comment: A few commenters opposed CMS's proposal and stated that newborns exposed to communicable diseases often require care and treatment well above that of a normal newborn in terms of requiring increased evaluation, monitoring, testing, and prophylactic treatment. Some commenters stated that these newborns are not ''normal newborns'' due to the specific exposures they have had. These commenters listed a number of communicable diseases as examples and indicated the specific interventions such as evaluations, screenings, assessments, extra monitoring, laboratory studies, prophylactic treatments and sometimes isolation that can be required to prevent disease or complications when contact or (suspected) exposure occurs. Another commenter noted that there is a substantial difference in the FY 2023 proposed relative weights between MS–DRG 795 and MSDRG 794 and stated that ''exposure only'' cases fall in between the two MS–DRGs in terms of resource utilization. This commenter stated that a review of the cases at their facility shows that cases assigned to MS–DRG 794 with only a diagnosis code describing contact with and (suspected) exposure to communicable diseases driving the MS–DRG assignment had longer lengths of stay and higher charges than cases assigned to MS–DRG 795, while having shorter lengths of stay and lower charges than other cases assigned to MS–DRG 794 with diagnoses describing conditions other than contact with and (suspected) exposure driving the MS–DRG assignment. This commenter also stated that they believed that the five ICD–10–CM diagnosis codes from ICD–10–CM category Z20 currently listed in the ''only secondary diagnosis'' list under MS–DRG 795 are currently inappropriately included and requested that either the 13 codes for contact with and (suspected) exposure remain assigned to MS–DRG 794 and the five codes currently in MS–DRG 795 be reassigned to MS–DRG 794 or a new MS–DRG be created that would include newborns that fall into the ''exposure only'' category, with a relative weight that falls somewhere between the relative weights of MS–DRG 794 and 795 to accurately capture resource utilization.

Response: We thank the commenters for their feedback. Our clinical advisors reviewed the commenters' concerns. While our clinical advisors agree that patients exposed to communicable diseases can require workup or prophylactic treatment, they continue to state these patients are distinct from patients with identified signs or symptoms of a suspected problem or diagnosed with having that communicable disease. Our clinical advisors noted that the subset of newborns with a principal or secondary diagnosis listed in the logic list for MS–DRG 794 (Neonate with Other Significant Problems) are clinically distinct and often represent a more severe set of patients. Accordingly, our clinical advisors continue to believe that the five other diagnosis codes describing contact with, and suspected exposure to, communicable diseases are appropriately assigned to the ''only secondary diagnosis'' list under MS–DRG 795, and also continue to support adding the 13 diagnosis codes listed previously to the logic of MS–DRG 795 for clinical consistency. We appreciate the commenters' feedback suggesting further review of the newborn MS–DRGs and agree that these groupings warrant special consideration. As discussed in prior rulemaking, we generally do not adopt the same approach to refine the maternity and newborn MS–DRGs because of the extremely low volume of Medicare patients there are in these DRGs.

After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to add the 13 diagnosis codes listed previously that describe contact with and (suspected) exposure to communicable diseases to the ''only secondary diagnosis'' list under MS–DRG 795 (Normal Newborn), without modification, for FY 2023.

In addition, as discussed in the proposed rule, as we examined the GROUPER logic that would determine an assignment of cases to MS–DRGs in MDC 15, we noted the logic for MS–DRG 790 (Extreme Immaturity or Respiratory Distress Syndrome Neonate) includes ICD–10–CM diagnosis codes that describe extremely low birth weight newborn, extreme immaturity of newborn and respiratory distress syndrome of newborn. We referred the reader to the ICD–10 MS–DRG Version 39.1 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) for complete documentation of the GROUPER logic for MS–DRG 790. We stated that during our review of the diagnosis codes assigned to these MS–DRGs, we identified three diagnosis codes that do not exist in the logic for MS–DRG 790. The three diagnosis codes and their current MS–DRG assignments are listed in the following table.

ICD-10-CM Code	Description	MS-DRG
P07.00	Extremely low birth weight newborn, unspecified weight	791 and 792 (Prematurity with and without Major Problems, respectively)
P07.20	Extreme immaturity of newborn, unspecified weeks of gestation	795 (Normal Newborn)
P07.26	Extreme immaturity of newborn, gestational age 27 completed weeks	791 and 792 (Prematurity with and without Major Problems, respectively)

We stated our clinical advisors reviewed this grouping issue and noted that while virtually every neonate under 1000 grams, which is the definition of extremely low birth weight (ELBW), will have a weight documented somewhere in the medical record, in the rare instance that it is not, if the diagnosis documented by the provider is ''ELBW'' the neonate would be in a higher risk category. Our clinical advisors also noted that whereas weight is measured with high precision, gestational age is more complicated. With the exception of in vitro fertilization, gestational age is an estimate. Our clinical advisors stated similar to documentation of ''ELBW'', if the diagnosis documented by the provider is ''extreme immaturity of newborn'' the neonate would be in a higher risk category. These diagnoses

describe conditions that require advanced care and resources similar to other conditions already assigned to the logic of MS–DRG 790 even in cases where the birth weight, or weeks of gestation, are unspecified.

For clinical consistency, our clinical advisors supported the addition of these three diagnosis codes to the GROUPER logic list for MS–DRG 790. Therefore, we proposed to reassign ICD–10–CM diagnosis codes P07.00, P07.20 and P07.26 to MS–DRG 790, effective October 1, 2022 for FY 2023.

Comment: Commenters expressed support for CMS' proposal to reassign ICD–10–CM diagnosis codes P07.00, P07.20 and P07.26 to MS–DRG 790.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–CM diagnosis codes P07.00, P07.20 and P07.26 to MS–DRG 790, without modification, effective October 1, 2022 for FY 2023.

11. Review of Procedure Codes in MS–DRGs 981 Through 983 and 987 Through 989

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine. We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

In addition to this internal review, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS–DRGs to which the procedure codes are assigned.

Based on the results of our review of the claims data from the September 2021 update of the FY 2021 MedPAR file, as well as our review of the requests that we received to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we proposed to move the cases reporting the procedures and/or principal diagnosis codes described in this section of this rule from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis or procedure is assigned.

a. Embolization of Portal and Hepatic Veins

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28170), we received a request to reassign cases with a principal diagnosis from MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas) when reported with procedures involving the embolization of a hepatic or portal vein from MS–DRGs 981, 982 and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 423, 424, and 425 (Other Hepatobiliary or Pancreas Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 07.

We noted that in ICD–10–PCS, the root operation selected to code embolization procedures is dependent on the objective of the procedure. If the objective of an embolization procedure is to completely close a vessel, the root operation Occlusion is coded. ICD–10–PCS procedure codes 06L43DZ (Occlusion of hepatic vein with intraluminal device, percutaneous approach) or 06L83DZ (Occlusion of portal vein with intraluminal device, percutaneous approach) may be reported to describe embolization procedures to completely close off a hepatic or portal vein with an intraluminal device. If the objective of an embolization procedure is to narrow the lumen of a vessel, the root operation Restriction is coded. ICD–10–PCS procedure codes 06V43DZ (Restriction of hepatic vein with intraluminal device, percutaneous approach) or 06V83DZ (Restriction of portal vein with intraluminal device, percutaneous approach) may be reported to describe embolization procedures to narrow or partially occlude a hepatic or portal vein with an intraluminal device.

These four ICD–10–PCS procedure codes, as well as their MDC assignments, are listed in the table:

ICD-10-PCS Code	Description	MDC
06L43DZ	Occlusion of hepatic vein with intraluminal device, percutaneous approach	05, 06, 21, 24
06L83DZ	Occlusion of portal vein with intraluminal device, percutaneous approach	05, 06, 21, 24
06V43DZ	Restriction of hepatic vein with intraluminal device, percutaneous approach	05, 21, 24
06V83DZ	Restriction of portal vein with intraluminal device, percutaneous approach	05, 21, 24

We stated in the proposed rule that our analysis of this grouping issue confirmed that when a procedure code describing the percutaneous occlusion or restriction of the hepatic or portal vein with intraluminal device is reported with a principal diagnosis from MDC 07, these cases group to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). Whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

As noted in the proposed rule, to understand the resource use for the subset of cases reporting procedure codes 06L43DZ, 06L83DZ, 06V43DZ or 06V83DZ with a principal diagnosis from MDC 07 that are currently grouping to MS–DRGs 981, 982, and

983, we examined claims data from the September 2021 update of the FY 2021 MedPAR file for the average length of stay and average costs for these cases. Our findings are shown in the following table:

MS-DRGs 981-983: Cases Reporting Procedure Describing Percutaneous Occlusion or Restriction of Hepatic or Portal Vein with Intraluminal Device with Principal Diagnosis from MDC 07				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
981	All cases	22,967	12.1	$35,790
	Cases reporting 06L43DZ; 06L83DZ; 06V43DZ or 06V83DZ with a principal diagnosis from MDC 07	23	13.9	$45,634
982	All cases	10,465	5.9	$19,803
	Cases reporting 06L43DZ; 06L83DZ; 06V43DZ or 06V83DZ with a principal diagnosis from MDC 07	10	8.6	$16,772
983	All cases	1,905	2.7	$13,877
	Cases reporting 06L43DZ; 06L83DZ; 06V43DZ or 06V83DZ with a principal diagnosis from MDC 07	1	1	$15,140

We also examined the data for cases in MS–DRGs 423, 424, and 425, and our findings are shown in the following table:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
423 – All cases	1,222	10.9	$32,145
424 – All cases	547	6	$19,514
425 – All cases	98	2.9	$12,113

As noted in the proposed rule, while the claims analysis based on the September 2021 update of the FY 2021 MedPAR file identified only 34 cases for which these procedures were reported with a principal diagnosis from MDC 07 resulting in assignment to MS–DRGs 981 through 983, and the average length of stay and average costs for these cases vary in comparison to the average length of stay and average costs of all cases in MS–DRGs 423, 424, and 425, given the clinical indications for hepatic or portal vein embolization procedures, such as to induce regrowth on one side of the liver in advance of a planned hepatic resection on the other side, we stated we believed it was clinically appropriate to add these procedure codes describing the percutaneous occlusion or restriction of the hepatic or portal vein with intraluminal device to MS–DRGs 423, 424, and 425 in MDC 07. Our clinical advisors stated that these procedures are clearly related to the principal diagnoses as they are procedures performed for hepatobiliary diagnoses, namely hepatocellular carcinoma and liver metastases, so it is clinically appropriate for the procedures to group to the same MDC as the principal diagnoses. Our clinical advisors also stated the procedures describing the percutaneous occlusion or restriction of the hepatic or portal vein with intraluminal device are consistent with the existing procedure codes included in the logic for case assignment to MS–DRGs 423, 424, and 425.

Therefore, we proposed to add ICD–10–PCS procedure codes 06L43DZ, 06L83DZ, 06V43DZ and 06V83DZ to MDC 07 in MS–DRGs 423, 424 and 425. Under this proposal, cases reporting procedure codes 06L43DZ, 06L83DZ, 06V43DZ or 06V83DZ in conjunction with a principal diagnosis code from MDC 07 would group to MS–DRGs 423, 424 and 425.

Comment: Commenters expressed support for CMS' proposal to add ICD–10–PCS procedure codes 06L43DZ, 06L83DZ, 06V43DZ and 06V83DZ to MDC 07 in MS–DRGs 423, 424 and 425. A commenter stated that this proposal is in line with resources utilized in performing the procedures and also helps organizations better manage their Program for Evaluating Payment Patterns Electronic Report (PEPPER) data related to DRG 981 and 982.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS procedure codes 06L43DZ, 06L83DZ, 06V43DZ and 06V83DZ to MDC 07 in MS–DRGs 423, 424 and 425, without modification, effective October 1, 2022 for FY 2023.

b. Percutaneous Excision of Hip Muscle

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28171), we received a request to examine cases reporting a procedure describing

percutaneous biopsies of muscle. The requestor stated that when procedures describing the percutaneous excision of the left hip muscle for diagnostic purposes are reported with a principal diagnosis from MDC 06 (Diseases and Disorders of the Digestive System) such as K68.12 (Psoas muscle abscess), the cases are assigned to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). However, when procedures describing the percutaneous excision of the retroperitoneum for diagnostic purposes are reported with the same principal diagnosis of psoas muscle abscess, the cases are assigned to medical MS–DRGs 371, 372, and 373 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC, with CC, and without CC/MCC, respectively). The requestor stated the cases at their facility with a principal diagnosis of psoas muscle abscess when reported with a procedure describing a biopsy of the left muscle had an average length of stay comparable to other cases assigned to MS–DRGs 371, 372, and 373. The requestor provided ICD–10–PCS procedure code 0KBP3ZX (Excision of left hip muscle, percutaneous approach, diagnostic) in its request and recommended that CMS evaluate the assignment of procedure code 0KBP3ZX because procedures describing the percutaneous excision of the left hip muscle for diagnostic purposes appear to be related to a diagnosis of psoas muscle abscess.

We stated in the proposed rule that in order to analyze this request, we first identified the similar ICD–10–PCS procedure codes that also describe the excision of hip muscle. We noted that under the ICD–10–PCS procedure classification, biopsy procedures are identified by the 7th digit qualifier value ''diagnostic'' in the code description. The four ICD–10–PCS procedure codes that describe the excision of hip muscle, as well as their MDC assignments, are listed in the table:

ICD-10-PCS Code	Description	MDC
0KBN3ZX	Excision of right hip muscle, percutaneous approach, diagnostic	08
0KBN3ZZ	Excision of right hip muscle, percutaneous approach	01; 08; 09; 21; 24
0KBP3ZX	Excision of left hip muscle, percutaneous approach, diagnostic	08
0KBP3ZZ	Excision of left hip muscle, percutaneous approach	01; 08; 09; 21; 24

We stated in the proposed rule that our analysis of this grouping issue confirmed that when procedure codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX or 0KBP3ZZ are reported with a principal diagnosis from MDC 06, such as K68.12, these cases group to MS–DRGs 981, 982, and 983. As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in a MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

As noted in the proposed rule, we examined the claims data from the September 2021 update of the FY 2021 MedPAR file to identify cases reporting procedure codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, or 0KBP3ZZ with a principal diagnosis of K68.12 (Psoas muscle abscess) that are currently grouping to MS–DRGs 981, 982, and 983. Our findings are shown in this table:

MS-DRGs 981-983: Cases Reporting Procedures Describing Excision of Hip Muscle with a Principal Diagnosis of Psoas Muscle Abscess				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
981	All cases	22,967	12.1	$35,790
	Cases reporting excision of hip muscle with principal diagnosis of K68.12	2	7.5	$12,388
982	All cases	10,465	5.9	$19,803
	Cases reporting excision of hip muscle with principal diagnosis of K68.12	4	9.8	$13,810
983	All cases	1,905	2.7	$13,877
	Cases reporting excision of hip muscle with principal diagnosis of K68.12	1	2	$7,781

As shown, in our analyses of the claims data for MS–DRGs 981 through 983, we found a total of seven cases reporting procedures describing excision of hip muscle with a principal diagnosis of K68.12 in the September 2021 update of the FY 2021 MedPAR file.

We stated in the proposed rule that to further evaluate this issue, we examined claims data from the September 2021 update of the FY 2021 MedPAR file for cases reporting any one of the four procedure codes (0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, or 0KBP3ZZ) in MS–DRGs

981 through 983 with a principal diagnosis from MDC 06. Our findings are shown in the following table.

MS-DRGs 981-983: Cases Reporting Procedures Describing Excision of Hip Muscle with Principal Diagnosis from MDC 06				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
981	All cases	22,967	12.1	$35,790
	Cases reporting excision of hip muscle with any principal diagnosis from MDC 06	5	9.6	$15,599
982	All cases	10,465	5.9	$19,803
	Cases reporting excision of hip muscle with any principal diagnosis from MDC 06	8	8.5	$12,346
983	All cases	1,905	2.7	$13,877
	Cases reporting excision of hip muscle with any principal diagnosis from MDC 06	1	2	$7,781

As shown, in our analyses of the claims data for MS–DRGs 981 through 983, we found a total of 14 cases reporting procedures describing excision of hip muscle with a principal diagnosis from MDC 06 in the September 2021 update of the FY 2021 MedPAR file.

We also stated in the proposed rule that we examined the data for cases in MS–DRGs 371, 372, and 373, and our findings are shown in the following table:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
371 – All cases	11,415	6.9	$13,284
372 – All cases	15,680	4.6	$8,072
373 – All cases	3,090	3.3	$5,860

As discussed in the proposed rule, we reviewed these procedures and our clinical advisors stated that procedures that describe the percutaneous excision of hip muscle are not surgical in nature and would not be the main reason for inpatient hospitalization or be considered the principal driver of resource expenditure. Our clinical advisors stated although a correlation cannot usually be made between procedures performed in general anatomic regions, such as the retroperitoneum, and procedures performed in specific body parts, such as muscle, because procedures coded with general anatomic region body parts represent a broader range of procedures that cannot be coded to a specific body part, they agreed that in this instance procedures that describe the percutaneous excision of hip muscle should have the same designation as the ICD–10–PCS procedure codes that describe the percutaneous excision of the retroperitoneum that are currently designated as non-O.R. procedures.

We stated that our clinical advisors reviewed this analysis and believed that, for clinical coherence and consistency, it would be appropriate to designate ICD–10–PCS codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, and 0KBP3ZZ as non-O.R. procedures.

Therefore, we proposed to remove codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, and 0KBP3ZZ from the FY 2023 ICD–10 MS–DRGs Version 40 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedures would no longer impact MS–DRG assignment. Cases reporting procedure codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, and 0KBP3ZZ in conjunction with a principal diagnosis code from MDC 06 would group to MS–DRGs 371, 372, and 373.

Comment: Some commenters expressed support for CMS' proposal to remove codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, and 0KBP3ZZ from the FY 2023 ICD–10 MS–DRGs Version 40 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures.

Response: We appreciate the commenters' support.

Comment: A commenter opposed CMS' proposal to designate ICD–10–PCS codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, and 0KBP3ZZ as non-O.R. procedures and stated that they did not believe this proposal was warranted based on the work involved in performing the procedures.

Response: We thank the commenter for their feedback. Our clinical advisors reviewed the commenter's concerns and continue to support a non-O.R. designation for procedure codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, and

0KBP3ZZ that describe the percutaneous excision of hip muscle. Our clinical advisors continue to state that procedure codes that describe the percutaneous excision of hip muscle are not surgical in nature and these procedures should have the same designation as the ICD–10–PCS procedure codes that describe the percutaneous excision of the retroperitoneum that are currently designated as non-O.R. procedures.

After consideration of the public comments we received, for the reasons stated, we are finalizing our proposal to remove codes 0KBN3ZX, 0KBN3ZZ, 0KBP3ZX, and 0KBP3ZZ from the FY 2023 ICD–10 MS–DRGs Version 40 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, without modification, effective October 1, 2022 for FY 2023. Under this final policy, these procedures will no longer impact MS–DRG assignment.

In addition, as discussed in the proposed rule, we also conduct an internal review and consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate for the cases to be reassigned from one of the MS–DRG groups to the other. In the proposed rule, we stated that based on the results of our review of the claims data from the September 2021 update of the FY 2021 MedPAR file we did not identify any cases for reassignment. We also stated we did not receive any requests suggesting reassignment. Therefore, for FY 2023 we did not propose to move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

Comment: Commenters expressed support for CMS' decision to not propose to move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the structure of MS–DRGs 981 through 983 and MS–DRGs 987 through 989 for FY 2023 without modification.

12. Operating Room (O.R.) and Non-O.R. Issues

a. Background

Under the IPPS MS–DRGs (and former CMS MS–DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed. Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.).

Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS- DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, our clinical advisors recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.D.14 of the preamble of this final rule, we are making Table 6B.—New Procedure Codes—FY 2023 available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We also refer readers to the ICD–10 MS–DRG Version 39.1 Definitions Manual at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multi year project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non O.R.-designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule that as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R.

procedures may warrant an O.R. type of designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of specific surgical approaches to evaluate whether to subdivide specific MS DRGs based on a specific surgical approach. We plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58540 through 58541), we provided a summary of the comments we had received in response to our request for feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration.

We stated in the proposed rule that in consideration of the ongoing PHE, we continue to believe it may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review. Additional time is also necessary as we continue to develop our process and methodology. Therefore, we stated that we will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

Comment: Commenters supported CMS' plan to continue to conduct the comprehensive, systematic review of the ICD–10–PCS codes that includes a process for determining when a procedure is designated as O.R. or non-O.R. These commenters expressed support of CMS' decision to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review in consideration of the ongoing PHE. A commenter stated they appreciate that CMS is taking the appropriate time before deciding whether and how to restructure the current O.R. and non-O.R. designations. Another commenter acknowledged that O.R. and non-O.R. designation determinations are a substantial undertaking that may significantly restructure many MS–DRGs.

Response: We thank the commenters for their support and appreciate their acknowledgement of the magnitude of this effort.

Comment: Other commenters stated that designation of O.R. versus non-O.R. may no longer be the most critical differentiator between resource-intensive procedures for MS–DRG purposes. These commenters noted that medical practice is changing and presently, there are increasingly complex and resource-intensive procedures performed by hospitals that do not involve the use of an operating room. A commenter stated that because of technological advances, sophisticated resource-intensive procedures are no longer confined to the operating room setting.

Other commenters highlighted stem cell transplants (SCT), Chimeric Antigen Receptor (CAR) T-cell therapy, and other novel cell and gene therapies as examples of therapeutic interventions that have similar or greater resource utilization and complexity than some O.R. designated procedures, while not being currently designated as O.R. procedures themselves. Another commenter noted that some procedures performed in interventional radiology suites and cardiac catheterization labs can utilize more advanced equipment and supplies than procedures performed in a traditional operating room with minimally installed equipment. As part of the broader and continuing conversation about future MS–DRG assignments and designations for these procedures and therapies, these commenters encouraged CMS to consider how other factors influence resource utilization, and recommended CMS consider questions such as whether:

- certain types of interventions, such as the administration of certain complex drugs/biologics or therapies (for example, radiation therapy), that demonstrate higher costs and resource utilization, warrant consideration of a designation as an O.R. procedure or another equivalent designation?
- certain types of procedures and therapies make up a substantial percentage of the costs within a particular MS–DRG?
- there is an average amount of cost within the relative weight of a MS–DRG that represents significant resource utilization and complexity?
- complex infusion-type administration of novel and potentially curative cell and gene therapies should be considered for new category of MS–DRGs, to be added to the current categories of Pre-MDC MS–DRGs, Surgical MS–DRGs and Medical MS–DRGs?

Response: CMS appreciates the commenters' feedback and recommendations as to factors to consider in evaluating O.R. designations. As stated previously, we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room. We agree with commenters and believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10. As discussed in the proposed rule, we are exploring alternatives on how we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is available in the ICD–10 claims data. We continue to develop our process and methodology, and will provide more detail in future rulemaking.

Comment: Several commenters suggested that CMS work closely with physician specialty societies and interested parties to identify the most important drivers of complexity and resource use in the hospital setting. Other commenters suggested CMS engage the broader community by convening town halls or listening sessions. A few commenters suggested that CMS allow sufficient time for provider review and stated that thorough data analysis with provider input is critical to allow for appropriate insight in provider comments. A commenter recommended that CMS be transparent in its methodology, identify criteria or metrics used to determine what does and does not constitute significant resource utilization and complexity across MS–DRGs, and be receptive to public opinion. Another commenter stated that they look forward to CMS providing more detail on this analysis and expressed that they would appreciate advanced notice for comment in future rulemaking regarding the proposed methodology for conducting this review.

Response: CMS appreciates this feedback. We note that CMS has already convened an internal workgroup comprised of clinicians, coding specialists and other policy analysts, and we look forward to further feedback from the public. Recognizing sufficient time is needed to provide feedback on what factors or criteria to consider in determining whether a procedure should be designated as an O.R. procedure in the ICD–10–PCS classification system, we have provided opportunity for the public to provide feedback beginning with the FY 2018 final rule and we continue to solicit input. We encourage the public to submit comments on other factors to consider in our refinement efforts to recognize and differentiate consumption of resources for the ICD–10 MS–DRGs timely for consideration. We will also

explore additional means of eliciting feedback, and will notify the public of any such other opportunities for communication and comment in the future. Once we are in a position to provide more detail on this analysis and the methodology for conducting this comprehensive review, we will do so in future rulemaking.

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28174 through 28175), we received the following requests regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures. In this section of this rule, as we did in the proposed rule, we summarize these requests and address why we are not considering a change to the designation of these codes at this time and, further, respond to the public comments we received regarding these requests.

We received a request to change the designation of all ICD–10–PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs, from non-O.R. to O.R. According to the requestor, thoracoscopic and laparoscopic procedures are always performed in the operating room under general anesthesia. In the proposed rule, we stated we believed additional time was needed to fully examine the numerous ICD–10–PCS codes in the classification that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs as there are over 19,000 ICD–10–PCS codes in the classification that describe procedures performed using a percutaneous endoscopic approach. As we have signaled in prior rulemaking, the designation of an O.R. procedure encompasses more than the physical location of the hospital in which the procedure may be performed. We also examine if, and in what way, the performance of the procedure affects the resource expenditure in those admissions in the inpatient setting, in addition to examining other clinical factors such as procedure complexity, and need for anesthesia administration as well as other types of sedation. We stated we will continue to evaluate the ICD–10–PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs as we conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes.

Comment: A commenter stated that they agreed with the request to change the designation of all lCD–10–PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs from non-O.R. to O.R. and stated that these procedures would likely occur in an operating room under general anesthesia. Another commenter stated that while they did not dispute that there may be over 19,000 ICD–10–PCS codes that describe procedures performed using a percutaneous endoscopic approach, they believed that this list could be whittled down substantially by considering only codes describing procedures performed on thoracic and abdominal organs. This commenter stated that even with a smaller list utilizing the criteria they suggested, they could not think of a thoracoscopic or laparoscopic procedure that would not require general anesthesia and be performed in an operating room and urged CMS to designate all ICD–10–PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs as operating room procedures.

Response: We appreciate the commenters' feedback. We also appreciate the commenter's suggestion, however, as stated in the proposed rule, and in prior rulemaking, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. Our clinical advisors recommended that rather than evaluating the procedure codes describing diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs in isolation, analysis should be performed for this subset of procedure codes across the MS–DRGs, as part of the comprehensive procedure code review. As a component of our broader comprehensive procedure code review, we are also reviewing the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is available in the ICD–10 claims data. Therefore, after consideration of the public comments we received, and for the reasons discussed, we are not making changes in this final rule to the designation of all ICD–10–PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs, from non-O.R. to O.R. We will provide more detail on the comprehensive procedure code review and the methodology for conducting this review in future rulemaking.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44892 through 44895) CMS finalized the proposal to remove the 22 codes that describe the open drainage of subcutaneous tissue and fascia listed in the following table from the ICD–10 MS–DRGs Version 39.1 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this finalization, these procedures no longer impact MS–DRG assignment.

ICD-10-PCS Code	Description
0J900ZZ	Drainage of scalp subcutaneous tissue and fascia, open approach
0J910ZZ	Drainage of face subcutaneous tissue and fascia, open approach
0J940ZZ	Drainage of right neck subcutaneous tissue and fascia, open approach
0J950ZZ	Drainage of left neck subcutaneous tissue and fascia, open approach
0J960ZZ	Drainage of chest subcutaneous tissue and fascia, open approach
0J970ZZ	Drainage of back subcutaneous tissue and fascia, open approach
0J980ZZ	Drainage of abdomen subcutaneous tissue and fascia, open approach
0J990ZZ	Drainage of buttock subcutaneous tissue and fascia, open approach
0J9B0ZZ	Drainage of perineum subcutaneous tissue and fascia, open approach
0J9C0ZZ	Drainage of pelvic region subcutaneous tissue and fascia, open approach
0J9D0ZZ	Drainage of right upper arm subcutaneous tissue and fascia, open approach
0J9F0ZZ	Drainage of left upper arm subcutaneous tissue and fascia, open approach
0J9G0ZZ	Drainage of right lower arm subcutaneous tissue and fascia, open approach
0J9H0ZZ	Drainage of left lower arm subcutaneous tissue and fascia, open approach
0J9J0ZZ	Drainage of right hand subcutaneous tissue and fascia, open approach
0J9K0ZZ	Drainage of left hand subcutaneous tissue and fascia, open approach
0J9L0ZZ	Drainage of right upper leg subcutaneous tissue and fascia, open approach
0J9M0ZZ	Drainage of left upper leg subcutaneous tissue and fascia, open approach
0J9N0ZZ	Drainage of right lower leg subcutaneous tissue and fascia, open approach
0J9P0ZZ	Drainage of left lower leg subcutaneous tissue and fascia, open approach
0J9Q0ZZ	Drainage of right foot subcutaneous tissue and fascia, open approach
0J9R0ZZ	Drainage of left foot subcutaneous tissue and fascia, open approach

In the FY 2022 final rule we noted that the designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as O.R. procedures was a result of a replication error in transitioning to ICD–10. This replication error led to ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia being listed as comparable translations for ICD–9–CM code 83.09 (Other incision of soft tissue), which was designated as a non-extensive O.R. procedure under the ICD–9–CM MS–DRGs Version 32, as opposed to being listed as comparable translations for ICD–9–CM code 86.04 (Other incision with drainage of skin and subcutaneous tissue) which was designated as a non-O.R. procedure under the ICD–9–CM MS–DRGs Version 32. We stated in the FY 2022 final rule that designating the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as non-O.R. procedures would result in a more accurate replication of the comparable procedure, under the ICD–9–CM MS–DRGs Version 32 which was 86.04, not 83.09 and is more aligned with current shifts in treatment practices.

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, we received a request to re-examine this change in designation. According to the requestor, open procedures for the drainage of subcutaneous tissue and fascia are indeed typically performed in the operating room under general anesthesia and involve making incisions through the subcutaneous tissue into fascia for therapeutic drainage, breaking up of loculations, and irrigation. We stated that while our clinical advisors did not disagree with the requestor that these procedures can involve making incisions through the subcutaneous tissue into fascia, they continued to state procedures describing the open drainage of subcutaneous tissue and fascia can now be safely performed in the outpatient setting and when performed during a hospitalization, they are typically performed in conjunction with another O.R. procedure. For the reasons discussed in the FY 2022 final rule, our clinical advisors stated that the non-O.R. designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as finalized in the FY 2022 final rule better reflects the associated technical complexity and hospital resource use of these procedures.

Comment: Some commenters opposed the non-O.R. designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as finalized in the FY 2022 final rule and urged that these codes be designated as O.R. procedures for FY 2023. These commenters stated that procedure codes that describe the open drainage of subcutaneous tissue and fascia are indeed performed in the operating room under general anesthesia, are surgical in nature, and an O.R. designation would more accurately capture the utilization of resources. A commenter stated that a review of the cases at their facility shows that approximately 80% of the procedures describing open drainage of subcutaneous tissue and fascia are performed in an O.R. setting requiring anesthesia, with a much lesser percentage performed at the bedside. Another commenter noted in the FY 2018 IPPS proposed rule, these same 22 ICD–10–PCS codes were identified and a commenter opposed the proposal to re-designate these codes at that time. In response to the issues raised by this commenter, CMS agreed in the FY 2018

IPPS final rule to maintain the designation of the 22 procedure codes. This commenter stated the rationale to maintain these 22 codes as O.R. procedures has not changed and that there is no safe way to effectively drain an infection involving the subfascial plane without the resources of an operating room.

Response: Our clinical advisors reviewed the commenters' concerns and continue to state that treatment practices have continued to shift since FY 2018 rulemaking. As stated in the FY 2022 final rule in response to similar comments, procedures describing the open drainage of subcutaneous tissue and fascia can now be safely performed in the outpatient setting and when performed during a hospitalization, it is typically in conjunction with another O.R. procedure. In cases where procedures describing open drainage of subcutaneous tissue and fascia are the only procedures performed in an admission, the admission is quite likely due to need for IV antibiotics as opposed to the need for operating room resources in an inpatient setting.

We refer the reader to Table 6P.1f associated with this final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the data analysis of cases reporting the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia in the September 2021 update of the FY 2021 MedPAR file. We note that within each MDC, the MS–DRGs are divided into medical and surgical categories. In general, surgical MS–DRGs are further defined based on the precise surgical procedure performed while the medical MS–DRGs are further defined based on the precise principal diagnosis for which a patient was admitted to the hospital. In Table 6P.1f associated with this final rule, column B displays the category of each MS–DRG in MS–DRG GROUPER Version 39.1. The letter M is used to designate a medical MS–DRG and the letter P is used to designate a surgical MS–DRG. As shown in the table, when the procedure codes that describe the open drainage of the subcutaneous tissue and fascia are reported, approximately 70% of the MS–DRGs assigned are classified as surgical MS–DRGs which indicates at least one procedure code designated as an O.R. procedure was also reported in these cases. We refer the reader to the ICD–10 MS–DRG Version 39.1 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/MS-DRGClassifications-and-Software*) for complete documentation of the GROUPER logic for the listed MS–DRGs.

Our clinical advisors continue to state that procedure codes that describe the open drainage of subcutaneous tissue and fascia do not reflect the technical complexity or resource intensity in comparison to other procedures that are designated as O.R. procedures. They also continue to state that the non-O.R. designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as finalized in the FY 2022 final rule better reflects the associated technical complexity and hospital resource use of these procedures.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are not making changes in this final rule to the designation of the 22 codes that describe the open drainage of subcutaneous tissue and fascia listed in the previous table.

13. Changes to the MS–DRG Diagnosis Codes for FY 2023

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (NonCC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as a MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when assigning severity levels to new codes and when receiving requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the proposed severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 final rule, we generally did not finalize our proposed changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16– (Resistance to antimicrobial drugs) from a NonCC to a CC. We stated that postponing adoption of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the proposed

severity level designation changes for FY 2020.

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/Downloads/10082019ListingSessionTrasncriptandQandAsandAudioFile.zip* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the mathematical data generated using claims from the FY 2018 MedPAR file describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554), we discussed our plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles and plan to present the findings and proposals in future rulemaking. The nine guiding principles are as follows:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation or management of care or both.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for a complete discussion of our response to public comments regarding the nine guiding principles.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175 through 25180), as another interval step in our comprehensive review of the severity designations of ICD–10–CM diagnosis codes, we requested public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we were considering adopting for FY 2022. Specifically, we noted we were considering changing the severity level designation of ''unspecified'' diagnosis codes to a NonCC where there are other codes available in that code subcategory that further specify the anatomic site. As summarized in the FY 2022 IPPS/LTCH PPS final rule, many commenters expressed concern with the potential severity level designation changes overall and recommended that CMS delay any possible change to the designation of these codes to give hospitals and their physicians time to prepare. After careful consideration of the public comments we received, we maintained the severity level designation of the ''unspecified'' diagnosis codes currently designated as a CC or MCC where there are other codes available in that code subcategory that further specify the anatomic site for FY 2022. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44916 through 44926) for a complete discussion of our response to public comments regarding the potential severity level designation changes. Instead, for FY 2022, we finalized a new Medicare Code Editor (MCE) code edit for ''unspecified'' codes, effective with discharges on and after April 1, 2022. We stated we believe finalizing this new edit would provide additional time for providers to be educated while not affecting the payment the provider is eligible to receive. We refer the reader to section II.D.14.e. of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943) for the complete discussion.

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, as this new edit became effective beginning with discharges on and after April 1, 2022, we stated our clinical advisors believed it was appropriate to not propose to change the designation of any ICD–10–CM diagnosis codes, including the unspecified codes that are subject to the ''Unspecified Code'' edit, as we continue our comprehensive CC/MCC analysis to allow interested parties the time needed to become acclimated to the new edit.

Comment: Commenters stated that they appreciate and agree with CMS' decision not to propose any further changes to the designation of any ICD–10–CM diagnosis codes, including the unspecified codes, at this time. These commenters recommended that CMS allow one to two full years of data availability before proposing any additional changes to the designation of any ICD–10–CM diagnosis code, given that the new MCE edit was recently implemented on April 1, 2022 and stated that having one to two full years of data will afford more meaningful analysis in future rulemaking considerations as part of the comprehensive CC/MCC analysis.

Response: We appreciate the commenters' support. With respect to the commenters who suggested allowing one to two full years of data availability before proposing any additional changes, we appreciate the feedback and will take these suggestions under consideration.

We continue to solicit feedback regarding the guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. We have made available on the CMS website updated impact on resource use files so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 MedPAR file, the FY 2020 MedPAR file and the FY 2021 MedPAR files. The link to these files is posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*. When providing additional feedback or comments, we encourage the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code. We also continue to be interested in receiving feedback on how we might otherwise foster the documentation and reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition to more accurately reflect each health care encounter and improve the reliability and validity of the coded data. Interested parties can submit any comments and recommendations for FY 2024 by

October 20, 2022 via the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home*.

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28177), for new diagnosis codes approved for FY 2023, consistent with our annual process for designating a severity level (MCC, CC or NonCC) for new diagnosis codes, we first review the predecessor code designation, followed by review and consideration of other factors that may be relevant to the severity level designation, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We noted that this process does not automatically result in the new diagnosis code having the same designation as the predecessor code. We refer the reader to section II.D.14 of this final rule for the discussion of the proposed changes to the ICD–10–CM and ICD–10–PCS coding systems for FY 2023.

c. Requested Changes to Severity Levels

In the FY 2023 IPPS/LTCH PPS proposed rule, we noted that we received several requests to change the severity level designations of specific ICD–10–CM diagnosis codes, including a request to analyze a subset of the social determinants of health (SDOH) diagnosis codes. We stated our clinical advisors believed it was appropriate to consider these requests in connection with our continued comprehensive CC/MCC analysis in future rulemaking, rather than proposing to change the designation of individual ICD–10–CM diagnosis codes at this time. However, we refer the reader to section II.D.13.d for further discussion related to the diagnosis codes describing social determinants of health. As discussed in the proposed rule and noted earlier in this section, we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles. We will consider these individual requests received for changes to severity level designations as we continue our comprehensive CC/MCC analysis and will provide more detail in future rulemaking.

d. Request for Information on Social Determinants of Health Diagnosis Codes

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28177 through 28181), we solicited public comments on how the reporting of diagnosis codes in categories Z55–Z65 may improve our ability to recognize severity of illness, complexity of service, and/or utilization of resources under the MS–DRGs as described further in this section. Consistent with the Administration's goal of advancing health equity for all, including members of historically underserved and under-resourced communities, as described in the President's January 20, 2021 Executive Order 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [13] we stated we were also interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity.

Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[14] These circumstances or determinants influence an individual's health status and can contribute to wide health disparities and inequities. While SDOH do not describe current illnesses or injuries at the individual level, they are widely recognized as important potential predictors of risk for developing medical conditions like heart disease, diabetes, and obesity. In ICD–10–CM, the Z codes found in Chapter 21 represent reasons for encounters, and are provided for occasions when circumstances other than a disease, injury or external cause classifiable to categories A00–Y89 are recorded as 'diagnoses' or 'problems'. The subset of Z codes that describe the social determinants of health are found in categories Z55–Z65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances). These codes describe a range of issues related—but not limited—to education and literacy, employment, housing, ability to obtain adequate amounts of food or safe drinking water, and occupational exposure to toxic agents, dust, or radiation. We noted that effective October 1, 2021, the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) added 11 new diagnosis codes describing SDOH to provide additional information regarding determinants such as housing, food insecurity, and transportation. In addition, section I.B.14 of the FY 2022 ICD–10–CM Official Guidelines for Coding and Reporting was updated to provide clarification of the term ''clinician'' in reporting codes related to social determinants of health and clarified the documentation that can be utilized to assign SDOH codes when included in the official medical record. In this context, ''clinicians'' other than the patient's provider refer to ''healthcare professionals permitted, based on regulatory or accreditation requirements or internal hospital policies, to document in a patient's official medical record.'' [15]

As stated in the proposed rule, reporting SDOH Z codes in inpatient claims data could enhance quality improvement activities, track factors that influence people's health, and provide further insight into existing health inequities.[16] [17] [18] More routine collection of SDOH Z codes could also likely improve coordination within hospitals to utilize the data across their clinical care and discharge planning teams, including with post-acute partners. CMS has heard from interested parties about a number of reasons for why there may be less routine documentation and reporting of SDOH in the inpatient setting. First, Z codes are not required to be reported by inpatient hospitals and generally do not affect MS–DRG assignment. Rather, these codes are currently reported voluntarily by providers when and if supported in the medical record

[13] *Available at: https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[14] *Available at: https://health.gov/healthypeople/objectives-and-data/social-determinants-health.*

[15] *Available at: https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2022/10cmguidelines-FY2022-April%201%20update%202-3-22.pdf.*

[16] Maksut JL, Hodge C, Van CD, Razmi, A, & Khau MT. Utilization of Z Codes for Social Determinants of Health among Medicare Fee-For-Service Beneficiaries, 2019. Office of Minority Health (OMH) Data Highlight No. 24. Centers for Medicare & Medicaid Services (CMS), Baltimore, MD, 2021.

[17] Truong HP, Luke AA, Hammond G, Wadhera RK, Reidhead M, Joynt Maddox KE. Utilization of Social Determinants of Health ICD–10 Z-Codes Among Hospitalized Patients in the United States, 2016–2017. Med Care. 2020;58(12):1037–1043. doi:10.1097/MLR.0000000000001418.

[18] Wark K, Cheung K, Wolter E, Avey JP. Engaging stakeholders in integrating social determinants of health into electronic health records: A scoping review. International Journal of Circumpolar Health. 2021 Jan 1;80(1):1943983.

documentation. As such, consistent protocols may not be in place for documenting and reporting. Second, many of the circumstances captured through SDOH Z codes are dependent on the willingness of patients to discuss personal social, economic, or environmental conditions. Providers may or may not be able to reliably document certain circumstances,[19] as a result, in the medical records. There are also questions of how bias can play into screening for SDOH and how systemic bias within the health care system can play a role in this process.[20] CMS has also heard of the significant pressures on provider time, and whether providers have access to comprehensive care and coordination teams, including social workers, who may be more appropriately skilled to assess certain SDOH.

Given that SDOH diagnosis codes describe economic and environmental circumstances faced by patients and often correlate with substantial variance in health outcomes,[21] more widely adopted consistent documentation and reporting in the inpatient setting could better identify non-medical factors affecting health and track progress toward addressing them. Doing so could also aid in work toward formulating more comprehensive and actionable policies to address health equity and promote the highest quality, best-value care for all beneficiaries.

As we discuss more fully later in this section of this final rule, as we did in the proposed rule, we believe reporting of SDOH Z codes may also better determine the resource utilization for treating patients experiencing these circumstances to help inform whether a change to the severity designation of these codes would be clinically warranted as we continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles.

There are 96 diagnosis codes that describe the social determinants of health found in categories Z55–Z65. These 96 diagnosis codes for which we solicited comments as described in the proposed rule are shown in Table 6P.5a associated with the proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). We note we also made available the data describing the impact on resource use when reported as a secondary diagnosis for all 96 ICD–10–CM Z codes that describe the social determinants of health from categories Z55–Z65. These data are consistent with data historically used to mathematically measure impact on resource use for secondary diagnoses, and the data which we plan to use in combination with application of the nine guiding principles as we continue the comprehensive CC/MCC analysis.

In Table 6P.5a associated with the proposed rule, column C displays the FY 2021 severity level designation for these diagnosis codes in MS–DRG GROUPER Version 38.1. Column D displays CMS's current FY 2022 severity level designation in MS–DRG GROUPER Version 39.1. Columns E–N show data on the impact on resource use generated using discharge claims from the September 2021 update of the FY 2021 MedPAR file and MS–DRG GROUPER Version 39.1. For further information on the data on the impact on resource use as displayed in Columns E–N, we refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of the methodology utilized to mathematically measure the impact on resource use. Also, as discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/Downloads/10082019ListingSessionTrasncriptandQandAsandAudioFile.zip* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the data describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session. We note that the supplementary file that was made available for the listening session contains the mathematical data for the impact on resource use generated using claims from the FY 2018 MedPAR file. We have also made available on the CMS website updated impact on resource use files so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 MedPAR file, FY 2020 MedPAR file and the FY 2021 MedPAR files.

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described the categorization of diagnoses as an MCC, a CC, or a NonCC, accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. As such, the designation of CC or MCC is intended to account for the increased resources required to address a condition as a secondary diagnosis. In Version 39.1, the 96 diagnosis codes that describe the social determinants of health from categories Z55–Z65 have a severity designation of NonCC.

In the proposed rule, we noted that if SDOH Z codes are not consistently reported in inpatient claims data, our methodology utilized to mathematically measure the impact on resource use, as described previously, may not adequately reflect what additional resources were expended by the hospital to address these SDOH circumstances in terms of requiring clinical evaluation, extended length of hospital stay, increased nursing care or monitoring or both, and comprehensive discharge planning. In the proposed rule, we sought public comment on whether CMS should consider requiring more robust documentation and claims data reporting to inform the impact on resource use these determinants have on caring for patients affected by these circumstances in an inpatient setting and inform our decision-making in a future year in determining the most appropriate CC subclass (NonCC, CC, or MCC) assignment for each SDOH Z code as a secondary diagnosis. We also sought public comment on developing protocols to standardize the screening for SDOH for all patients, and then consistently document and report such codes and on whether such protocols should vary based on certain factors, such as hospital size and type. For instance, we noted in the proposed rule that we recognized that hospitals have different mixes of patients and volume of patients, and as such, may have

[19] Garg A, Boynton-Jarrett R, Dworkin PH. Avoiding the Unintended Consequences of Screening for Social Determinants of Health. JAMA. 2016;316(8):813–814. doi:10.1001/jama.2016.9282.

[20] Egede LE, Walker RJ, Williams JS. Intersection of Structural Racism, Social Determinants of Health, and Implicit Bias With Emergency Physician Admission Tendencies. JAMA Netw Open. 2021;4(9):e2126375. doi:10.1001/jamanetworkopen.2021.26375.

[21] Commission on Social Determinants of Health. *Closing the gap in a generation: health equity through action on the social determinants of health: final report of the commission on social determinants of health.* World Health Organization, 2008.

different staffing resources to devote to proper documentation and coding of SDOH. In particular, we stated we were interested in hearing the perspectives of different sized hospitals in both urban and rural settings, and hospitals disproportionately serving members of historically underserved and under-resourced communities in regard to their experience with reporting of SDOH. We also stated we were additionally interested in learning how reporting SDOH Z codes may be used to inform community health need assessment activities required by non-profit hospitals.

In the proposed rule, we also recognized that there is a potential for different uses and complexity in appropriately determining and reporting the full range of Z codes. For instance, certain code categories like Z62 (Problems related to upbringing) and Z63 (Other problems related to principal support group, including family circumstances) may require specialized clinical training to diagnose and document, which may not be the primary purpose of the inpatient admission. Category Z57 describes occupational exposure to risk factors, which also may not be apparent in most inpatient admissions and would rely upon the patient providing this information voluntarily. Category Z60 (Problems related to social environment) also describes problems of adjustment to life-cycle transitions, which also may or may not be readily apparent or discussed by the patient in relation to the inpatient admission.

Thus, we sought comment on which specific SDOH Z codes were most likely to influence (that is, increase) hospital resource utilization related to inpatient care, including any supporting information that correlates inpatient hospital resource use to specific SDOH Z codes. In the proposed rule, we stated CMS believed a potential starting point for discussion was consideration of the SDOH Z diagnosis codes describing homelessness. Homelessness can be reasonably expected to have an impact on hospital utilization.[22] Healthcare needs for patients experiencing homelessness may be associated with increased resource utilization compared to other patients due to difficulty finding discharge destinations to meet the patient's multifaceted needs which can result in longer inpatient stays and can have financial impacts for hospitals.[23] Longer hospital stays for these patients [24] can also be associated with increased costs because patients experiencing homelessness are less able to access care at early stages of illness, and also may be exposed to communicable disease and harsh climate conditions, resulting in more severe and complex symptoms by the time they are admitted to hospitals, potentially leading to worse health outcomes. We stated in the proposed rule that patients experiencing homelessness can also be disproportionately affected by mental health diagnoses and issues with substance use disorders. In addition, patients experiencing homelessness may have limited or no access to prescription medicines or over-the-counter medicines, including adequate locations to store medications away from the heat or cold,[25] and studies have shown difficulties adhering to medication regimens among persons experiencing homeless.[26] Patients experiencing homelessness may also face challenges in accessing transplants and clinicians may defer care because of the uncertain post-acute discharge.

To further examine the diagnosis codes that describe SDOH, in the proposed rule we reviewed the data on the impact on resource use for diagnosis code Z59.0 (Homelessness) when reported as a secondary diagnosis to facilitate discussion for the purposes of the comment solicitation. We noted that prior to FY 2022, homelessness was one of the more frequently reported codes that describe social determinants of health. We also noted that effective FY 2022, the subcategory was expanded and now includes codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and code Z59.02 (Unsheltered homelessness).

In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19243 through 19244), as part of our proposal to change the severity level designations for 1,492 ICD–10–CM diagnosis codes, we proposed to change the severity level designation of code Z59.0 (Homelessness) from NonCC to CC. We stated that because the C1 value (C1 = 1.5964) in the table was generally close to 2, the data suggested that when reported as a secondary diagnosis, the resources involved in caring for a patient experiencing homelessness supported increasing the severity level from a NonCC to a CC. In the FY 2020 IPPS/LTCH PPS proposed rule, we also stated our clinical advisors reviewed these data and believed the resources involved in caring for these patients are more aligned with a CC. As noted in section II.D.13.b of the proposed rule and this final rule, many commenters expressed concern with the proposed severity level designation changes overall and consequently we generally did not finalize our proposed changes to the severity designations for the 1,492 ICD–10–CM diagnosis codes, at that time. However, the proposal to change the severity designation of code Z59.0 specifically did receive mostly supportive comments. We stated in the proposed rule that many commenters stated that a patient experiencing homelessness requires significant coordination of social services along with their health care. Another commenter also recommended that CMS expand the change in designation to all the codes in category Z59, not just code Z59.0. Another commenter, while indicating their support of the proposal, noted that it is unclear that the status/condition would result in increased hospital resource use.

As discussed in the proposed rule, our proposal in FY 2020 was based on the data for the impact on resource use generated using claims from the FY 2018 MedPAR file. The following table reflects the impact on resource use data generated using claims from the FY 2019 MedPAR file, FY 2020 MedPAR file and the FY 2021 MedPAR file, respectively, for the diagnosis code that describes homelessness as a NonCC. We noted there is currently no data for codes Z59.01 (Sheltered homelessness) and code Z59.02 (Unsheltered homelessness) as these codes became effective on October 1, 2021. Again, we refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our historical approach to mathematically evaluate the extent to which the presence of an ICD–

[22] Koh HK, O'Connell JJ. Improving Health Care for Homeless People. JAMA. 2016;316(24):2586–2587. doi:10.1001/jama.2016.18760.

[23] Canham SL, Custodio K, Mauboules C, Good C, Bosma H. Health and Psychosocial Needs of Older Adults Who Are Experiencing Homelessness Following Hospital Discharge. Gerontologist. 2020 May 15;60(4):715–724. doi: 10.1093/geront/gnz078. PMID: 31228238. *https://pubmed.ncbi.nlm.nih.gov/31228238/*.

[24] Hwang SW, Weaver J, Aubry T. Hospital costs and length of stay among homeless patients admitted to medical, surgical, and psychiatric services. Med Care. 2011;49:350–354. *https://journals.lww.com/lww-medicalcare/Fulltext/2019/01000/Trends,_Causes,_and_Outcomes_of_Hospitalizations.4.aspx*.

[25] Sun R (AHRQ), Karaca Z (AHRQ), Wong HS (AHRQ). Characteristics of Homeless Individuals Using Emergency Department Services in 2014. HCUP Statistical Brief #229. October 2017. Agency for Healthcare Research and Quality, Rockville, MD. *www.hcup-us.ahrq.gov/reports/statbriefs/sb229-Homeless-ED-Visits-2014.pdf*.

[26] Coe, Antoinette B. Coe et al. ''Medication Adherence Challenges Among Patients Experiencing Homelessness in a Behavioral Health Clinic. *https://journals.lww.com/lww-medicalcare/Fulltext/2019/01000/Trends,_Causes,_and_Outcomes_of_Hospitalizations.4.aspx*.

10–CM code as a secondary diagnosis resulted in increased hospital resource use, and the explanation of the columns in the table.

FY	ICD-10-CM Code	Description	Tota1 Count	Cnt1	C1	Cnt2	C2	Cnt3	C3
2019	Z59.0	Homelessness	43,405	7,022	1.6723	22,336	2.2963	14,047	3.1374
2020	Z59.0	Homelessness	44,609	6,393	1.8374	22,416	2.1964	15,800	3.0879
2021	Z59.00	Homelessness, unspecified	37,919	5,225	1.4299	18,158	2.0823	14,536	3.0710

As shown in the table, we examined data for the diagnosis code(s) that describe homelessness as a NonCC in FY 2019 through FY 2021. When examining diagnosis code Z59.0 (Homelessness), the value in column C1 is closer to 2.0 than to 1.0 in FY 2019 and FY 2020, though we noted that we did not use FY 2020 data for rate setting purposes in light of impacts related to the PHE for COVID–19 as described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44778). The data suggests that when homelessness is reported as a secondary diagnosis, the resources involved in caring for these patients are more aligned with a CC than a NonCC or an MCC, as explained in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159). However, in FY 2021, the C1 value is generally closer to 1, which suggest the resources involved in caring for patients experiencing homelessness are more aligned with a NonCC severity level than a CC or an MCC severity level. We also noted fluctuations in the C1 values year to year. We stated we were uncertain if the data from FY 2021, in particular, reflect fluctuations that may be a result of the public health emergency or even reduced hospitalizations of certain conditions. We also stated we were uncertain if homelessness may be underreported when there is not an available field on the claim when other diagnoses are reported instead. We sought public comment on these possibilities, particularly to inform our understanding of the trend of the C1 value.

As we have stated in prior rulemaking, these mathematical constructs are used in conjunction with the judgment of our clinical advisors to classify each secondary diagnosis reviewed. We presented these data to highlight that the resources expended in caring for patients reported to be affected by a SDOH such as homelessness during an inpatient hospitalization may not be consistently expressed in the inpatient claims data and to demonstrate how reporting the SDOH Z codes could more accurately reflect the health care encounter and improve the reliability and validity of the coded data.

In summary, we stated we would appreciate public comment on these issues, including on the following questions:

- How the reporting of certain Z codes—and if so, which Z codes [27]—may improve our ability to recognize severity of illness, complexity of service, and utilization of resources under the MS–DRGs?
- Whether CMS should require the reporting of certain Z codes—and if so, which ones—to be reported on hospital inpatient claims to strengthen data analysis?
- The additional provider burden and potential benefits of documenting and reporting of certain Z codes, including potential benefits to beneficiaries.
- Whether codes in category Z59 (Homelessness) have been underreported and if so, why? In particular, we stated we were interested in hearing the perspectives of large urban hospitals, rural hospitals, and other hospital types in regard to their experience. We also sought comments on how factors such as hospital size and type might impact a hospital's ability to develop standardized consistent protocols to better screen, document and report homelessness.

As discussed in the proposed rule, we stated that the comments we receive on these issues may also be informative as we evaluate whether to develop a proposal in future rulemaking to change the severity level designation of the diagnosis codes describing homelessness from NonCC to CC and whether other SDOH, as described by Z codes, are also appropriate candidates to be proposed for designation as CCs.

We noted that examining the severity level designation of diagnosis codes is just one area to possibly support documentation and reporting of SDOH in the inpatient setting. We stated we were also interested in ideas from the public on how the MS–DRG classification can be utilized in agency wide efforts to advance health equity, expand access, drive high-quality, person-centered care, and promote affordability and sustainability in the Medicare program. Specifically, we invited public comment on ways the MS–DRG classification can be useful in addressing the challenges of defining and collecting accurate and standardized self-identified socioeconomic information for the purposes of reporting, measure stratification, and other data collection efforts. We stated we were interested in learning more about the potential benefits and challenges associated with the collection of SDOH data in the inpatient setting. Feedback on the limitations and barriers providers could experience as they consider more robust documentation and reporting would also help inform our development of appropriately tailored efforts that address and mitigate barriers for all hospital types across communities and patient mixes. We stated we would take commenters' feedback into consideration in future policy development.

In this FY 2023 IPPS/LTCH PPS final rule, we present a summation of the comments we received in response to our request for information on SDOH diagnosis codes, including how the reporting of SDOH diagnosis codes may improve our ability to recognize severity of illness, complexity of service, and/or utilization of resources under the MS–DRGs, as well as how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data, including in support of efforts to advance health equity. We thank commenters for sharing their views and their willingness to support CMS in these efforts.

Comment: Many commenters applauded CMS' efforts to encourage documentation and reporting of SDOH diagnosis codes given the impact that social risks can have on health outcomes. These commenters stated that it is critical that physicians, other health care professionals, and facilities

[27] *https://www.cms.gov/files/document/zcodes-infographic.pdf.*

recognize the impact SDOH have on the health of their patients. Commenters stated that they agree that better reporting of these SDOH Z codes through inpatient claims could enhance coordination within hospitals across clinical care teams and discharge planning, and with post-acute care providers. A commenter stated that SDOH data can be extremely valuable and powerful tools to improve healthcare, and stated that they were confident that CMS' encouragement of the use of this data would lead to better healthcare for our country.

Some commenters stated that while the documentation and reporting of SDOH diagnosis codes is important to address healthcare inequities, the collection of this data may place significant burden on facilities and providers and have tremendous operational and technology impacts. Commenters stated that hospitals have demonstrated significant variability in screening capabilities and referral practices, and inpatient settings require additional time to develop screening protocols and ensure that screening results are documented in a place where they can be captured for claims. Other commenters stated assigning codes for SDOH can be a time-consuming and labor-intensive process, as many electronic health records (EHRs) do not have easy pathways to add a Z code to the problem or diagnosis list. Other commenters stated that one of the major challenges to providers is ensuring that SDOH information documented in the EHR and reported on the claim is accurate as patients' circumstances are ever changing. A commenter stated that it is not feasible for hospitals to screen for every SDOH due to the time and resources involved for both patients and providers and suggested that rather than require this process be repeated with each encounter, CMS should permit SDOH information to carry forward across encounters until new documentation supports removal or revision to the initial SDOH diagnosis codes to minimize the administrative burden. Commenters also stated that the challenge of increased documentation reviews by coding staff would be further exacerbated by staffing shortages within the industry, as well as coding productivity standards. A few commenters stated for rural hospitals, bandwidth is already low due to workforce shortages and heavy caseloads. These commenters stated that adding any screening and documentation processes for SDOH, on top of existing workloads, may require more than a physician or nurse and instead may require engaging a staff such as social workers or psychologists who may not be standard members of care teams at all rural hospitals.

Many commenters stated there was a lack of standard, nationally accepted definitions of the SDOH Z codes and that there are potential gaps that may come with the use of, and reporting related to SDOH Z codes. Other commenters stated that SDOH Z codes are informative but some descriptions lack specificity and may be too broad to distinctly capture enough detail around the type of care that the patient needs relative to their diagnosis and their SDOH challenges. Commenters also identified the lack of national data and exchange standards for capture of the SDOH Z codes as an additional barrier. Commenters stated that while fully supporting efforts to improve and increase the collection of SDOH data, they believed that other options exist that would make it feasible for hospitals of all sizes and types to consistently collect data in a standardized manner without creating undue burden and suggested that CMS consider developing a broader strategy for collecting SDOH data. A commenter specifically suggested that CMS coordinate with states, which are often requiring their own assessments to identify social risk and needs, to reduce burden. Another commenter stated that they believed that the creation of a new Hierarchical Condition Category for SDOH Z codes could help improve documentation efforts since, according to this commenter, organizations that treat these high-risk patients are reimbursed at higher rates than those patients who are not grouped into these HCCs.

Commenters recommended that CMS consider reimbursement incentives for documenting and reporting of SDOH Z codes to help health care providers build and sustain systemic screening and documentation, which will ultimately lead to better health for patients. Many commenters stated that they agree that codes in category Z59 (Homelessness) have been underreported and that increasing the severity level of the codes that describe homelessness from a NonCC to a CC could prompt more rigorous documentation and reporting. Commenters stated that they believe that homelessness involves a level of care in line with diagnoses currently designated as CCs. Some commenters stated that patients experiencing homelessness can often increase inpatient costs by creating discharge disposition challenges that lead to an extended length of stay. A few commenters noted that in their experience, extended lengths of stay were particularly high for patients experiencing homelessness who underwent surgery. Another commenter stated that based on their own analysis, homelessness has an effect on resource utilization on par with other diagnoses currently designated as MCCs but stated elevation to a CC is the most reasonable first step to help drive the reporting of these SDOH Z codes, and help drive subsequent, meaningful evaluation of outcomes.

Commenters encouraged CMS to examine other SDOH Z codes that describe circumstances such as food insecurity, lack of adequate food and drinking water, extreme poverty, lack of transportation and unemployment, to determine the hospital resource utilization related to addressing these factors and to analyze whether these SDOH Z codes should be considered for designation as CCs as well. Some commenters also pointed to conditions outside of the SDOH Z codes such as: medical debt, malnutrition, elder abuse and neglect, underdosing of medication, personal history of falling and awaiting organ transplant status as examples of other areas where fostering better documentation and reporting could improve health outcomes.

Other commenters expressed concern and stated that they believed that while some SDOH diagnoses could have some impact for MS–DRG assignment due to additional efforts needed around discharge planning, generally SDOH diagnoses should have limited impact on severity of illness. Rather, according to these commenters, the impact is more important for risk adjustment for population-based initiatives, such as a readmissions program. A commenter stated that simply elevating SDOH Z-codes to CCs and marginally increasing reimbursement will be inadequate to meaningfully drive CMS' stated equity mission. Another commenter noted that in some cases, patients experiencing circumstances described by SDOH Z codes may require social services support to address a need post-discharge, but the complexity of the inpatient clinical services is not affected. A commenter, while supportive of the consideration of the change in designation, expressed concern that increasing the severity level of the codes that describe homelessness from a NonCC to a CC could potentially lead to fraudulent or abusive coding practices in order to raise the payment rate for an encounter. Another commenter recommended that safeguards be put in place to disallow oversight agencies (such as Recovery Audit Contractors (RAC) and third-party

payer validations) from challenging MS–DRG assignment, and instead honor the reporting of the code when supported by documentation, especially in instances where homelessness might be the only complication or comorbidity coded.

While commending CMS' efforts, many commenters cautioned that mandating the reporting of SDOH Z codes could necessitate making changes to the institutional claim form. Currently, only 25 diagnoses are captured on the electronic claim form. Commenters noted that documenting and reporting the social and economic circumstances patients may be experiencing may require a substantial number of SDOH Z codes, and stated that this could lead to the crowding out of other diagnosis codes that also need to be captured on the claim form such as codes for medical diagnoses, comorbidities, Hierarchical Condition Category (HCC) coding, Hospital Acquired Conditions (HAC), and patient safety indicators (PSI) due to limited space.

Several commenters expressed concern and stated that they did not believe that CMS proposed a clear, compelling, or significant benefit to patients as a result of collecting this data. These commenters cautioned against requiring hospitals to implement the collection of sensitive information for the purposes of analysis, and asserted that CMS will be placing hospitals in the precarious position of asking sensitive and intimate social questions, while often not having solutions to mitigate or eliminate these risks, as they stated the documentation of social risks does not in and of itself improve health outcomes. A commenter stated that studies have shown that many providers are wary of screening for social needs, if they believe they do not also have the ability to make referrals or to connect patients to resources to address their needs. Other commenters expressed concern and stated it is counterproductive for hospitals to collect SDOH data without having resources and pathways in place to offer help. A few commenters stated that by requiring medical facilities to report this data, CMS is diverting resources and time from patient care and stated that CMS should not be pursing an initiative that is meant to collect data on non-medical information. A commenter stated that although the collection of SDOH information can occur during inpatient visits, documentation and reporting of this data may be actually best suited to outpatient office visits, where providers may have a greater opportunity to interact with their patients and the ability to consider more proactive approaches to help address their social needs.

Many other commenters also expressed concern and stated that while SDOH information can be useful for administrative use and payment adjustment, information about an individual's social risk and needs has been shown to be sensitive, and individuals are often hesitant to disclose this information for fear of bias, misuse, or discrimination. Commenters stated patients may not see the relevance of providing information to their providers related to SDOH that may not be directly applicable to why they are seeking care. These commenters stated that there are significant concerns from physicians, other providers, and patients about ''medicalizing'' SDOH in the electronic health record and stated mechanisms must be established to shield this sensitive information on certain forms, charts, health records, and discharge papers. Commenters noted that when SDOH Z codes are entered via an EHR or other form of collection, those results show up on the patient's after-visit summary, which may be concerning for patients. Commenters also expressed concern that SDOH Z codes may ''follow'' a patient for too many years and cause potential discrimination, bias, or other misunderstandings in the future. Commenters stated that hospitals must be equipped with tools to communicate the context of SDOH Z codes with patients at the point of screening or self-reporting so that patients understand the rationale for data collection and how it can help address their needs. Several commenters stated that CMS should also put in place Conditions of Participation requiring hospitals to train their staff on how this information can and cannot be used to prevent information being used in discriminatory pricing, care, or other purposes.

Many commenters stated that the most immediate and important action CMS could take to increase the use of SDOH Z codes is to finalize the evidence-based ''Screening for Social Drivers of Health'' and ''Screen Positive Rate for Social Drivers of Health'' measures proposed to be adopted in the Hospital Inpatient Quality Reporting (IQR) Program. These commenters stated that these measures create an opportunity to collect inpatient SDOH data at a scale that could significantly improve MS–DRGs' precision and ability to recognize severity and complexity of service and utilization of resources. Many commenters stated that absent these measures and associated data, SDOH Z codes will continue to be underreported and unreliable. We refer the reader to section IX.E.5.b of the preamble of the proposed rule and this final rule for further discussion regarding new measures for the Hospital IQR Program measure set. These commenters urged CMS to start with an incremental approach in requiring the reporting of SDOH Z codes and suggested that reporting should be optional or voluntary for at least two–three years to allow providers and CMS to gain experience in reporting and collecting this data. If the reporting of the SDOH Z codes becomes mandatory, these commenters recommended that the requirement start with the subset of SDOH Z codes that directly align with the social needs identified in the five core domains of the proposed measures.

Response: We again thank commenters for sharing their views and their willingness to support CMS in these efforts. We will take the commenters' feedback into consideration in future policy development.

e. Additions and Deletions to the Diagnosis Code Severity Levels for FY 2023

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28181) we noted the following tables identify the proposed additions and deletions to the diagnosis code MCC severity levels list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2023 and are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*

Table 6I.1—Proposed Additions to the MCC List—FY 2023;

Table 6I.2—Proposed Deletions to the MCC List—FY 2023;

Table 6J.1—Proposed Additions to the CC List—FY 2023; and

Table 6J.2—Proposed Deletions to the CC List—FY 2023.

Comment: Commenters agreed with the proposed additions and deletions to the MCC and CC lists as shown in tables 6I.1, 6I.2, 6J.1, and 6J.2 associated with the proposed rule.

Response: We appreciate the commenters' support.

The following tables associated with this final rule reflect the finalized severity levels under Version 40 of the ICD–10 MS–DRGs for FY 2023 and are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*; Table 6I. —Complete MCC List—FY 2023; Table

6I.1—Additions to the MCC List—FY 2023; Table 6I.2—Deletions to the MCC List—FY 2022; Table 6J.—Complete CC List—FY 2023; Table 6J.1—Additions to the CC List—FY 2023; and Table 6J.2—Deletions to the CC List—FY 2023.

f. CC Exclusions List for FY 2023

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) to preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another.
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another.
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 39.1 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, and includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as a MCC only for patients discharged alive; otherwise, they are assigned as a NonCC.

In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed additional changes to the ICD–10 MS–DRGs Version 40 CC Exclusion List based on the diagnosis and procedure code updates as discussed in section II.D.14. of the proposed rule and set forth in Tables 6G.1, 6G.2, 6H.1, and 6H.2 associated with the proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

As discussed in section II.D.14 of the preamble of this final rule, we are finalizing, without modification, the proposed assignments and designations for the diagnosis codes after consideration of the public comments received. Therefore, the finalized CC Exclusions List as displayed in Tables 6G.1, 6G.2, 6H.1, 6H.2, and 6K, associated with this final rule reflect the severity levels under V40 of the ICD–10 MS–DRGs. We have developed Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2023; Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2023; Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2023; and Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2023; and Table 6K. Complete List of CC Exclusions—FY 2023.

For Table 6G.1, each secondary diagnosis code finalized for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses finalized to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions finalized for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code finalized for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the finalized deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Tables 6G.1, 6G.2, 6H.1, and 6H.2 associated with this final rule are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

The ICD–10 MS–DRGs Version 40 CC Exclusion List is included as Appendix C of the Definitions Manual (available in two formats; text and HTML). The manuals are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* and each format includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link (HTML version) is provided to a collection of diagnosis codes which, when used as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as a MCC only for patients discharged alive; otherwise, they are assigned as a NonCC.

14. Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

To identify new, revised and deleted diagnosis and procedure codes, for FY 2023, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, and Table 6E.—Revised Diagnosis Code Titles for this final rule.

These tables are not published in the Addendum to the proposed rule or final rule, but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this final rule. As discussed in section II.D.17. of the preamble of the proposed rule and this final rule, the code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

We are finalizing the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, the finalized severity level designations for the new diagnosis codes are set forth in Table 6A. and the finalized O.R. status for the new procedure codes are set forth in Table 6B. Consistent with our established process, we examined the MS–DRG assignment and the attributes (severity level and O.R. status) of the predecessor diagnosis or procedure code, as applicable, to inform our finalized assignments and designations.

Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We note that this process does not automatically result in the new diagnosis or procedure code being proposed for assignment to the same MS–DRG or to have the same designation as the predecessor code.

We are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following tables associated with this final rule:

- Table 6A.—New Diagnosis Codes—FY 2023
- Table 6B.—New Procedure Codes—FY 2023
- Table 6C.—Invalid Diagnosis Codes—FY 2023
- Table 6D.—Invalid Procedure Codes—FY 2023
- Table 6E.—Revised Diagnosis Code Titles—FY 2023
- Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2023
- Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2023
- Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2023
- Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2023
- Table 6I.—Complete MCC List—FY 2023
- Table 6I.1.—Additions to the MCC List—FY 2023
- Table 6I.2.—Deletions to the MCC List—FY 2023
- Table 6J.—Complete CC List—FY 2023
- Table 6J.1.—Additions to the CC List—FY 2023
- Table 6J.2.—Deletions to the CC List—FY 2023
- Table 6K.—Complete List of CC Exclusions—FY 2023.

15. Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44936), we made available the FY 2022 ICD–10 MCE Version 39 manual file. The manual contains the definitions of the Medicare code edits, including a description of each coding edit with the corresponding diagnosis and procedure code edit lists. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 39 (and ICD–10 MS–DRGs) are posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

In the FY 2023 IPPS/LTCH PPS proposed rule, we discussed the proposals we were making based on our internal review and analysis. We noted that we did not receive any specific MCE requests by the November 1, 2021 deadline. In this FY 2023 IPPS/LTCH PPS final rule, we present a summation of the comments we received in response to the MCE proposals presented based on internal review and analyses in the proposed rule, our responses to those comments, and our finalized policies.

In addition, as a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, we routinely make changes to the MCE. In the past, in both the IPPS proposed and final rules, we have only provided the list of changes to the MCE that were brought to our attention after the prior year's final rule. We historically have not listed the changes we have made to the MCE as a result of the new and modified codes approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting. These changes are approved too late in the rulemaking schedule for inclusion in the proposed rule. Furthermore, although our MCE policies have been described in our proposed and final rules, we have not provided the detail of each new or modified diagnosis and procedure code edit in the final rule. However, we make available the finalized Definitions of Medicare Code Edits (MCE) file. Therefore, we are making available the FY 2023 ICD–10 MCE Version 40 Manual file, along with the link to the mainframe and computer software for the MCE Version 40 (and ICD–10 MS–DRGs), on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

a. External Causes of Morbidity Codes as Principal Diagnosis

In the MCE, the external cause codes (V, W, X, or Y codes) describe the circumstance causing an injury, not the nature of the injury, and therefore should not be used as a principal diagnosis.

As discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective as of October 1, 2022. Included in this table are codes currently subject to the External causes of morbidity codes as principal diagnosis edit. We proposed to delete the ICD–10–CM diagnosis codes shown in Table 6P.6a associated with the proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* that are currently subject to the External causes of morbidity codes as principal diagnosis edit since they will no longer be valid for reporting purposes.

Comment: Commenters agreed with CMS's proposal to remove the diagnosis codes listed in Table 6P.6a from the External Causes of Morbidity edit code list since they are no longer valid.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to delete the diagnosis codes listed in Table 6P.6a associated with the proposed rule from the External Causes of Morbidity edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

b. Age Conflict Edit

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-

old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Perinatal/Newborn—Age 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (for example, tetanus neonatorum, health examination for newborn under 8 days old).
- Pediatric—Age is 0–17 years inclusive (for example, Reye's syndrome, routine child health exam).
- Maternity—Age range is 9–64 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (for example, senile delirium, mature cataract).

(1) Maternity Diagnoses

Under the ICD–10 MCE, the Maternity diagnoses category for the Age conflict edit considers the age range of 9 to 64 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2022. We proposed to add new ICD–10–CM diagnosis codes to the edit code list for the Maternity diagnoses category as shown in Table 6P.6b associated with the proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* under the Age conflict edit.

Comment: Commenters agreed with CMS's proposal to add the diagnosis codes listed in Table 6P.6b to the Maternity diagnoses edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes as shown in Table 6P.6b associated with the proposed rule to the Maternity diagnoses edit code list.

In addition, as discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective as of October 1, 2022. We proposed to delete the following diagnosis codes from the Maternity diagnoses edit code list.

ICD-10-CM Code	Description
O35.0XX0	Maternal care for (suspected) central nervous system malformation in fetus, not applicable or unspecified
O35.0XX1	Maternal care for (suspected) central nervous system malformation in fetus, fetus 1
O35.0XX2	Maternal care for (suspected) central nervous system malformation in fetus, fetus 2
O35.0XX3	Maternal care for (suspected) central nervous system malformation in fetus, fetus 3
O35.0XX4	Maternal care for (suspected) central nervous system malformation in fetus, fetus 4
O35.0XX5	Maternal care for (suspected) central nervous system malformation in fetus, fetus 5
O35.0XX9	Maternal care for (suspected) central nervous system malformation in fetus, other fetus
O35.1XX0	Maternal care for (suspected) chromosomal abnormality in fetus, not applicable or unspecified
O35.1XX1	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 1
O35.1XX2	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 2
O35.1XX3	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 3
O35.1XX4	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 4
O35.1XX5	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 5
O35.1XX9	Maternal care for (suspected) chromosomal abnormality in fetus, other fetus

Comment: Commenters agreed with CMS's proposal to remove the diagnosis codes listed in the previous table from the Maternity diagnoses edit code list since they are no longer valid.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove the diagnosis codes listed in the previous table from the Maternity diagnoses edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

(2) Adult Diagnoses

Under the ICD–10 MCE, the Adult diagnoses category for the Age conflict edit considers the age range of 15 to 124 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved which will be effective with discharges on and after October 1, 2022. We proposed to add the following new ICD–10–CM diagnosis codes to the edit code list for the Adult diagnoses category under the Age conflict edit.

ICD-10-CM Code	Description
F01.511	Vascular dementia, unspecified severity, with agitation
F01.518	Vascular dementia, unspecified severity, with other behavioral disturbance
F01.52	Vascular dementia, unspecified severity, with psychotic disturbance
F01.53	Vascular dementia, unspecified severity, with mood disturbance
F01.54	Vascular dementia, unspecified severity, with anxiety
F01.A0	Vascular dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.A11	Vascular dementia, mild, with agitation
F01.A18	Vascular dementia, mild, with other behavioral disturbance
F01.A2	Vascular dementia, mild, with psychotic disturbance
F01.A3	Vascular dementia, mild, with mood disturbance
F01.A4	Vascular dementia, mild, with anxiety
F01.B0	Vascular dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.B11	Vascular dementia, moderate, with agitation
F01.B18	Vascular dementia, moderate, with other behavioral disturbance
F01.B2	Vascular dementia, moderate, with psychotic disturbance
F01.B3	Vascular dementia, moderate, with mood disturbance
F01.B4	Vascular dementia, moderate, with anxiety
F01.C0	Vascular dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.C11	Vascular dementia, severe, with agitation
F01.C18	Vascular dementia, severe, with other behavioral disturbance
F01.C2	Vascular dementia, severe, with psychotic disturbance
F01.C3	Vascular dementia, severe, with mood disturbance
F01.C4	Vascular dementia, severe, with anxiety
F03.911	Unspecified dementia, unspecified severity, with agitation
F03.918	Unspecified dementia, unspecified severity, with other behavioral disturbance
F03.92	Unspecified dementia, unspecified severity, with psychotic disturbance
F03.93	Unspecified dementia, unspecified severity, with mood disturbance
F03.94	Unspecified dementia, unspecified severity, with anxiety
F03.A0	Unspecified dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F03.A11	Unspecified dementia, mild, with agitation
F03.A18	Unspecified dementia, mild, with other behavioral disturbance
F03.A2	Unspecified dementia, mild, with psychotic disturbance
F03.A3	Unspecified dementia, mild, with mood disturbance
F03.A4	Unspecified dementia, mild, with anxiety
F03.B0	Unspecified dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F03.B11	Unspecified dementia, moderate, with agitation
F03.B18	Unspecified dementia, moderate, with other behavioral disturbance
F03.B2	Unspecified dementia, moderate, with psychotic disturbance
F03.B3	Unspecified dementia, moderate, with mood disturbance
F03B4	Unspecified dementia, moderate, with anxiety
F03.C0	Unspecified dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F03.C11	Unspecified dementia, severe, with agitation
F03.C18	Unspecified dementia, severe, with other behavioral disturbance
F03.C2	Unspecified dementia, severe, with psychotic disturbance
F03.C3	Unspecified dementia, severe, with mood disturbance
F03.C4	Unspecified dementia, severe, with anxiety
I25.112	Atherosclerotic heart disease of native coronary artery with refractory angina pectoris
I25.702	Atherosclerosis of coronary artery bypass graft(s), unspecified, with refractory angina pectoris
I25.712	Atherosclerosis of autologous vein coronary artery bypass graft(s) with refractory angina pectoris
I25.722	Atherosclerosis of autologous artery coronary artery bypass graft(s) with refractory angina pectoris
I25.732	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with refractory angina pectoris
I25.752	Atherosclerosis of native coronary artery of transplanted heart with refractory angina pectoris
I25.762	Atherosclerosis of bypass graft of coronary artery of transplanted heart with refractory angina pectoris
I25.792	Atherosclerosis of other coronary artery bypass graft(s) with refractory angina pectoris

Comment: Commenters agreed with CMS's proposal to add the diagnosis codes listed in the previous table to the Adult diagnoses edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Adult diagnoses edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

In addition, as discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective as of October 1, 2022. We proposed to delete the following codes from the Adult diagnoses edit code list.

ICD-10-CM Code	Description
F01.51	Vascular dementia with behavioral disturbance
F03.91	Unspecified dementia with behavioral disturbance

Comment: Commenters agreed with CMS's proposal to remove the diagnosis codes listed in the previous table from the Adult diagnoses edit code list since they are no longer valid.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove the diagnosis codes listed in the previous table from the Adult diagnoses edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

c. Sex Conflict Edit

In the MCE, the Sex conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

Comment: A commenter requested clarification on how the sex conflict edits consider patients who identify as transgender.

Response: The sex conflict edit under the MCE is consistent with 45 CFR 170.207(n) which states that birth sex must be coded as Male, Female or Unknown. Gender identity is a separate data element under 45 CFR 170.207(o). We note that any proposed changes to account for gender identity on the CMS–1450 form would need to be submitted to the National Uniform Billing Committee (NUBC) for consideration.

Comment: Another commenter expressed concerns about the existing ICD–10 codes and edits that appear to be sex specific (that is, male only or female only). According to the commenter, reporting of these codes for patients who identify as transgender may result in treatment being delayed or denied. The commenter acknowledged the necessity in aligning a patient's historical health data with that of their gender identity and personal anatomy, however, according to the commenter, removal of sex specific codes from the MCE would be beneficial for nonbinary people as well.

Another commenter stated that transgender individuals may be alienated and deterred from seeking medical care in the future as a result of inappropriate claims denial due to the Sex conflict edit. The commenter stated that obstetricians-gynecologists specifically have conveyed the need to document and report a patient's gender identity in combination with their sex to provide quality, patient-centered care. The commenter also stated they have made recommendations to the Office of the National Coordinator for Health Information Technology (ONC) to include the data element ''gender'' in its minimum certification criteria for electronic health records. The commenter recommended that CMS work with ONC to ensure that automated claim editors, like the MCE, do not require obstetrician-gynecologists and other health care professionals to misrepresent their patients' genders to provide the appropriate clinical care. Lastly, the commenter encouraged CMS to continue its efforts to reduce the administrative burden by adapting the MCE and other systems to fit the needs of all physicians and their patients.

Response: We appreciate the commenters' feedback. We intend to explore alternative options that may help to address the challenges described by the commenters with claims processing for individuals who identify as transgender or nonbinary.. We are interested in feedback and comments on other ways for which these issues could be considered from a process, systems and operational perspective. Comments should be directed to the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™), discussed in section II.D.1.b of the preamble of the proposed rule and this final rule at: *https://mearis.cms.gov/public/home* by October 20, 2022

(1) Diagnoses for Females Only Edit

As discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2022. We proposed to add new ICD–10–CM diagnosis codes to the edit code list for the Diagnoses for females only category as shown in Table 6P.6c associated with the proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* under the Sex conflict edit.

Comment: Commenters agreed with CMS's proposal to add the diagnosis codes listed in Table 6P.6c to the Diagnoses for females only edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes as shown in Table 6P.6c associated with the proposed rule to the Diagnoses for females only edit code list.

In addition, as discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective as of October 1, 2022. We proposed to delete the following codes from the Diagnoses for females only edit code list.

ICD-10-CM Code	Description
B37.3	Candidiasis of vulva and vagina
N80.0	Endometriosis of uterus
N80.1	Endometriosis of ovary
N80.2	Endometriosis of fallopian tube
N80.3	Endometriosis of pelvic peritoneum
N80.4	Endometriosis of rectovaginal septum and vagina
N80.5	Endometriosis of intestine
O35.0XX0	Maternal care for (suspected) central nervous system malformation in fetus, not applicable or unspecified
O35.0XX1	Maternal care for (suspected) central nervous system malformation in fetus, fetus 1
O35.0XX2	Maternal care for (suspected) central nervous system malformation in fetus, fetus 2
O35.0XX3	Maternal care for (suspected) central nervous system malformation in fetus, fetus 3
O35.0XX4	Maternal care for (suspected) central nervous system malformation in fetus, fetus 4
O35.0XX5	Maternal care for (suspected) central nervous system malformation in fetus, fetus 5
O35.0XX9	Maternal care for (suspected) central nervous system malformation in fetus, other fetus
O35.1XX0	Maternal care for (suspected) chromosomal abnormality in fetus, not applicable or unspecified
O35.1XX1	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 1
O35.1XX2	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 2
O35.1XX3	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 3
O35.1XX4	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 4
O35.1XX5	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 5
O35.1XX9	Maternal care for (suspected) chromosomal abnormality in fetus, other fetus

Comment: Commenters agreed with CMS's proposal to remove the diagnosis codes listed in the previous table from the Diagnoses for females only edit code list since they are no longer valid.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove the diagnosis codes listed in the previous table from the Diagnoses for female only edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

(2) Procedures for Males Only

As discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6B.—New Procedure Codes, lists the new procedure codes that have been approved to date which will be effective with discharges on and after October 1, 2022. Included in this table are the following procedure codes we proposed to add to the edit code list for the Procedures for males only category under the Sex conflict edit.

ICD-10-PCS Code	Code Description
04LE0CV	Occlusion of right prostatic artery with extraluminal device, open approach
04LE0DV	Occlusion of right prostatic artery with intraluminal device, open approach
04LE0ZV	Occlusion of right prostatic artery, open approach
04LE3CV	Occlusion of right prostatic artery with extraluminal device, percutaneous approach
04LE3DV	Occlusion of right prostatic artery with intraluminal device, percutaneous approach
04LE3ZV	Occlusion of right prostatic artery, percutaneous approach
04LE4CV	Occlusion of right prostatic artery with extraluminal device, percutaneous endoscopic approach
04LE4DV	Occlusion of right prostatic artery with intraluminal device, percutaneous endoscopic approach
04LE4ZV	Occlusion of right prostatic artery, percutaneous endoscopic approach
04LF0CW	Occlusion of left prostatic artery with extraluminal device, open approach
04LF0DW	Occlusion of left prostatic artery with intraluminal device, open approach
04LF0ZW	Occlusion of left prostatic artery, open approach
04LF3CW	Occlusion of left prostatic artery with extraluminal device, percutaneous approach
04LF3DW	Occlusion of left prostatic artery with intraluminal device, percutaneous approach
04LF3ZW	Occlusion of left prostatic artery, percutaneous approach
04LF4CW	Occlusion of left prostatic artery with extraluminal device, percutaneous endoscopic approach
04LF4DW	Occlusion of left prostatic artery with intraluminal device, percutaneous endoscopic approach
04LF4ZW	Occlusion of left prostatic artery, percutaneous endoscopic approach

Comment: Commenters agreed with CMS's proposal to add the diagnosis codes listed in the previous table to the Procedures for males only edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Procedures for males only

edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

d. Manifestation Code as Principal Diagnosis Edit

In the ICD–10–CM classification system, manifestation codes describe the manifestation of an underlying disease, not the disease itself, and therefore should not be used as a principal diagnosis.

As discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved which will be effective with discharges on and after October 1, 2022. Included in this table are the following new ICD–10–CM diagnosis codes that we proposed to add to the edit code list for the Manifestation code as principal diagnosis edit, because the disease itself would be required to be reported first.

ICD-10-CM Code	Description
F02.811	Dementia in other diseases classified elsewhere, unspecified severity, with agitation
F02.818	Dementia in other diseases classified elsewhere, unspecified severity, with other behavioral disturbance
F02.82	Dementia in other diseases classified elsewhere, unspecified severity, with psychotic disturbance
F02.83	Dementia in other diseases classified elsewhere, unspecified severity, with mood disturbance
F02.84	Dementia in other diseases classified elsewhere, unspecified severity, with anxiety
F02.A0	Dementia in other diseases classified elsewhere, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F02.A11	Dementia in other diseases classified elsewhere, mild, with agitation
F02.A18	Dementia in other diseases classified elsewhere, mild, with other behavioral disturbance
F02.A2	Dementia in other diseases classified elsewhere, mild, with psychotic disturbance
F02.A3	Dementia in other diseases classified elsewhere, mild, with mood disturbance
F02.A4	Dementia in other diseases classified elsewhere, mild, with anxiety
F02.B0	Dementia in other diseases classified elsewhere, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F02.B11	Dementia in other diseases classified elsewhere, moderate, with agitation
F02.B18	Dementia in other diseases classified elsewhere, moderate, with other behavioral disturbance
F02.B2	Dementia in other diseases classified elsewhere, moderate, with psychotic disturbance
F02.B3	Dementia in other diseases classified elsewhere, moderate, with mood disturbance
F02.B4	Dementia in other diseases classified elsewhere, moderate, with anxiety
F02.C0	Dementia in other diseases classified elsewhere, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F02.C11	Dementia in other diseases classified elsewhere, severe, with agitation
F02.C18	Dementia in other diseases classified elsewhere, severe, with other behavioral disturbance
F02.C2	Dementia in other diseases classified elsewhere, severe, with psychotic disturbance
F02.C3	Dementia in other diseases classified elsewhere, severe, with mood disturbance
F02.C4	Dementia in other diseases classified elsewhere, severe, with anxiety
I31.31	Malignant pericardial effusion in diseases classified elsewhere

Comment: Commenters agreed with CMS's proposal to add the diagnosis codes listed in the previous table to the Manifestation code as principal diagnosis edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Manifestation code as principal diagnosis edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

In addition, as discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective as of October 1, 2022. Included in this table is ICD–10–CM diagnosis code F02.81 (Dementia in other diseases classified elsewhere with behavioral disturbance), that is currently listed on the edit code list for the Manifestation code as principal diagnosis edit. We proposed to delete this code from the Manifestation code as principal diagnosis edit code list.

Comment: Commenters agreed with CMS's proposal to remove diagnosis code F02.81 from the Manifestation code as principal diagnosis edit code list since it is no longer valid.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove diagnosis code F02.81 from the Manifestation code as principal diagnosis edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

e. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual's health status but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable Principal Diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

As discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved which will be effective with discharges on and after October 1, 2022. Additionally, as discussed in section II.D.1.b of the preamble of the proposed rule and this final rule, we provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 40, so that the public could better analyze and understand the

impact of the proposals included in the proposed rule. We noted that at the time of the development of the test software, a subset of the listed codes (F01.511 through F01.C4) that were proposed for this edit were unable to be included and therefore, the test software does not reflect these codes. We proposed to add the following new ICD–10–CM diagnosis codes to the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM Code	Description
F01.511	Vascular dementia, unspecified severity, with agitation
F01.518	Vascular dementia, unspecified severity, with other behavioral disturbance
F01.52	Vascular dementia, unspecified severity, with psychotic disturbance
F01.53	Vascular dementia, unspecified severity, with mood disturbance
F01.54	Vascular dementia, unspecified severity, with anxiety
F01.A0	Vascular dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.A11	Vascular dementia, mild, with agitation
F01.A18	Vascular dementia, mild, with other behavioral disturbance
F01.A2	Vascular dementia, mild, with psychotic disturbance
F01.A3	Vascular dementia, mild, with mood disturbance
F01.A4	Vascular dementia, mild, with anxiety
F01.B0	Vascular dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.B11	Vascular dementia, moderate, with agitation
F01.B18	Vascular dementia, moderate, with other behavioral disturbance
F01.B2	Vascular dementia, moderate, with psychotic disturbance
F01.B3	Vascular dementia, moderate, with mood disturbance
F01.B4	Vascular dementia, moderate, with anxiety
F01.C0	Vascular dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.C11	Vascular dementia, severe, with agitation
F01.C18	Vascular dementia, severe, with other behavioral disturbance
F01.C2	Vascular dementia, severe, with psychotic disturbance
F01.C3	Vascular dementia, severe, with mood disturbance
F01.C4	Vascular dementia, severe, with anxiety
F06.70	Mild neurocognitive disorder due to known physiological condition without behavioral disturbance
F06.71	Mild neurocognitive disorder due to known physiological condition with behavioral disturbance
T43.655A	Adverse effect of methamphetamines, initial encounter
T43.655D	Adverse effect of methamphetamines, subsequent encounter
T43.655S	Adverse effect of methamphetamines, sequela
T43.656A	Underdosing of methamphetamines, initial encounter
T43.656D	Underdosing of methamphetamines, subsequent encounter
T43.656S	Underdosing of methamphetamines, sequela
Z03.83	Encounter for observation for suspected conditions related to home physiologic monitoring device ruled out
Z59.82	Transportation insecurity
Z59.86	Financial insecurity
Z59.87	Material hardship
Z71.87	Encounter for pediatric-to-adult transition counseling
Z71.88	Encounter for counseling for socioeconomic factors
Z72.823	Risk of suffocation (smothering) under another while sleeping
Z79.60	Long term (current) use of unspecified immunomodulators and immunosuppressants
Z79.61	Long term (current) use of immunemodulator
Z79.620	Long term (current) use of immunosuppressive biologic
Z79.621	Long term (current) use of calcineurin inhibitor
Z79.622	Long term (current) use of Janus kinase inhibitor
Z79623	Long term (current) use of mammalian target of rapamycin (mTOR) inhibitor
Z79.624	Long term (current) use of inhibitors of nucleotide synthesis

ICD-10-CM Code	Description
Z79.630	Long term (current) use of alkylating agent
Z79.631	Long term (current) use of antimetabolite agent
Z79.632	Long term (current) use of antitumor antibiotic
Z79.633	Long term (current) use of mitotic inhibitor
Z79.634	Long term (current) use of topoisomerase inhibitor
Z79.64	Long term (current) use of myelosuppressive agent
Z79.69	Long term (current) use of other immunomodulators and immunosuppressants
Z79.85	Long-term (current) use of injectable non-insulin antidiabetic drugs
Z87.61	Personal history of (corrected) necrotizing enterocolitis of newborn
Z87.68	Personal history of other (corrected) conditions arising in the perinatal period
Z87.731	Personal history of (corrected) tracheoesophageal fistula or atresia
Z87.732	Personal history of (corrected) persistent cloaca or cloacal malformations
Z87.760	Personal history of (corrected) congenital diaphragmatic hernia or other congenital diaphragm malformations
Z87.761	Personal history of (corrected) gastroschisis
Z87.762	Personal history of (corrected) prune belly malformation
Z87.763	Personal history of other (corrected) congenital abdominal wall malformations
Z87.768	Personal history of other specified (corrected) congenital malformations of integument, limbs and musculoskeletal system
Z91.110	Patient's noncompliance with dietary regimen due to financial hardship
Z91.118	Patient's noncompliance with dietary regimen for other reason
Z91.119	Patient's noncompliance with dietary regimen due to unspecified reason
Z91.190	Patient's noncompliance with other medical treatment and regimen due to financial hardship
Z91.198	Patient's noncompliance with other medical treatment and regimen for other reason
Z91.199	Patient's noncompliance with other medical treatment and regimen due to unspecified reason
Z91.A10	Caregiver's noncompliance with patient's dietary regimen due to financial hardship
Z91.A18	Caregiver's noncompliance with patient's dietary regimen for other reason
Z91.A20	Caregiver's intentional underdosing of patient's medication regimen due to financial hardship
Z91.A28	Caregiver's intentional underdosing of medication regimen for other reason
Z91.A3	Caregiver's unintentional underdosing of patient's medication regimen
Z91.A4	Caregiver's other noncompliance with patient's medication regimen
Z91.A5	Caregiver's noncompliance with patient's renal dialysis
Z91.A9	Caregiver's noncompliance with patient's other medical treatment and regimen

Comment: Commenters agreed with our proposal to add the diagnosis codes listed in the previous table to the Unacceptable Principal Diagnosis edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Unacceptable Principal Diagnosis edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

In addition, as discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective as of October 1, 2022. We proposed to delete the following codes from the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM Code	Description
Z87.76	Personal history of (corrected) congenital malformations of integument, limbs and musculoskeletal system
Z91.11	Patient's noncompliance with dietary regimen
Z91.19	Patient's noncompliance with other medical treatment and regimen

Comment: Commenters agreed with CMS's proposal to remove diagnosis codes Z87.76, Z91.11, and Z91.19 from the Unacceptable principal diagnosis edit code list since they are no longer valid.

Response: We appreciate the commenters' support. After consideration of the public comments we received, we are finalizing our proposal to remove the diagnosis codes listed in the previous table from the Unacceptable Principal Diagnosis edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

f. Unspecified Code

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943), we finalized the implementation of a new Unspecified code edit, effective with discharges on and after April 1, 2022. Unspecified codes exist in the ICD–10–CM classification for circumstances when documentation in the medical record does not provide the level of detail needed to support reporting a more specific code. However, in the inpatient setting, there should generally be very limited and rare circumstances for which the laterality (right, left, bilateral) of a condition is unable to be documented and reported.

As discussed in section II.D.14. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2022. We proposed to add the following new ICD–10–CM diagnosis codes to the Unspecified code edit code list.

ICD-10-CM Code	Description
S06.33AA	Contusion and laceration of cerebrum, unspecified, with loss of consciousness status unknown, initial encounter
S06.36AA	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness status unknown, initial encounter

Comment: Commenters agreed with our proposal to add the diagnosis codes listed in the previous table to the Unspecified code edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Unspecified code edit code list under the ICD–10 MCE Version 40, effective October 1, 2022.

g. Future Enhancement

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38053 through 38054) we noted the importance of ensuring accuracy of the coded data from the reporting, collection, processing, coverage, payment and analysis aspects. Subsequently, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20235) we stated that we engaged a contractor to assist in the review of the limited coverage and non-covered procedure edits in the MCE that may also be present in other claims processing systems that are utilized by our MACs. The MACs must adhere to criteria specified within the National Coverage Determinations (NCDs) and may implement their own edits in addition to what is already incorporated into the MCE, resulting in duplicate edits. The objective of this review is to identify where duplicate edits may exist and to determine what the impact might be if these edits were to be removed from the MCE.

We have also noted that the purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. As we indicated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41228), we are considering whether the inclusion of coverage edits in the MCE necessarily aligns with that specific goal because the focus of coverage edits is on whether or not a particular service is covered for payment purposes and not whether it was coded correctly.

Comment: A few commenters requested that CMS continue to include the existing coverage edits in the MCE. According to the commenters, the MACs software and systems may not be consistently updated and current, therefore, coding edits may trigger erroneously only to be dismissed on appeal when it is discovered that the code in question is covered under an NCD. The commenters stated their belief that the national MCE provides important safeguards for claims processing and coverage.

Response: We appreciate the commenters' feedback.

As we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion. As we have discussed in prior rulemaking, we recognize a need to further examine the current list of edits and the definitions of those edits.

We continue to encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™), discussed in section II.D.1.b of the preamble of the proposed rule and this final rule at: *https://mearis.cms.gov/public/home* by October 20, 2022.

16. Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the

average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this final rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we proposed to make for FY 2023, as discussed in section II.D. of the preamble of the proposed rule and this final rule, we are maintaining the existing surgical hierarchy for FY 2023.

17. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html.* The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.*

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The ICD–10 Coordination and Maintenance Committee holds its meetings in the spring and fall to update the codes and the applicable payment and reporting systems by October 1 or April 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 3 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website.

The Committee encourages participation in the previously mentioned process by health- related organizations and other interested parties. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed during the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS websites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers.

The Committee presented proposals for coding changes for implementation in FY 2023 at a public meeting held on September 14–15, 2021 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 15, 2021.

The Committee held its 2022 meeting on March 8–9, 2022. The deadline for submitting comments on the procedure code proposals that are being considered for an October 1, 2022 implementation was April 8, 2022. The deadline for submitting comments on the diagnosis code proposals that are being considered for an October 1, 2023 implementation was May 9, 2022. It was announced at this meeting that any new diagnosis and procedure codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by June 2022 would be included in the October 1, 2022 update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets. It was also announced at this meeting that we are changing the process for submitting requested updates to the ICD–10–PCS classification, beginning with the procedure code requests submitted for consideration for the September 13–14, 2022 ICD–10 Coordination and Maintenance Committee Meeting. As stated in section II.D.1.b. of the preamble of the proposed rule and this final rule, CMS is in the process of implementing a new electronic application intake system, MEARIS™. Effective January 5, 2022, MEARIS™ became available as an initial release for users to begin gaining familiarity with a

new approach and process to submit ICD–10–PCS procedure code requests. Information on this new approach for submitting an ICD–10–PCS code request can be accessed at: *https://mearis.cms.gov*. Effective March 1, 2022, the full release of MEARIS™ became active for ICD–10–PCS code request submissions. ICD–10–PCS code request submissions were due no later than June 10, 2022 to be considered for the September 13–14, 2022 ICD–10 Coordination and Maintenance Committee Meeting. Moving forward, CMS will only accept ICD–10–PCS code requests submitted via MEARIS™. Requests submitted through the ICDProcedureCodeRequest mailbox will no longer be considered. Within MEARIS™, we have built in several resources to support users, including a ''Resources'' section (available at *https://mearis.cms.gov/public/resources*) and technical support available under ''Useful Links'' at the bottom of the MEARIS™ site. Questions regarding MEARIS™ can be submitted to CMS using the form available under ''Contact'' at: *https://mearis.cms.gov/public/resources*.

As discussed in earlier sections of the preamble of this final rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, and Table 6E.—Revised Diagnosis Code Titles for this final rule, which are available via the internet on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps.* The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Therefore, although we make the code titles available through tables in association with the IPPS proposed and final rules, they are not subject to comment in the proposed or final rule. Because of the length of these tables, they are not published in the Addendum to the proposed or final rule. Rather, they are available via the internet as discussed in section VI. of the Addendum to the proposed rule and this final rule.

Recordings for the virtual meeting discussions of the procedure codes at the Committee's September 14–15, 2021 meeting and the March 8–9, 2022 meeting can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*. The materials for the discussions relating to diagnosis codes at the September 14–15, 2021 meeting and March 8–9, 2022 meeting can be found through the CDC website at: *http://www.cdc.gov/nchs/icd/icd10cm_maintenance.html*. These websites also provide detailed information about the Committee, including information on requesting a new code, participating in a Committee meeting, timeline requirements and meeting dates.

We encourage commenters to submit questions and comments on coding issues involving diagnosis codes via Email to: *nchsicd10cm@cdc.gov*.

Questions and comments concerning the procedure codes should be submitted via Email to: *ICDProcedureCodeRequest@cms.hhs.gov*.

We stated in the proposed rule that as a result of the ongoing COVID–19 public health emergency, the CDC implemented three new diagnosis codes describing immunization status related to COVID–19 into the ICD–10–CM effective with discharges on and after April 1, 2022.

The diagnosis codes are as follows:

ICD-10-CM Code	Description
Z28.310	Unvaccinated for COVID-19
Z28.311	Partially vaccinated for COVID-19
Z28.39	Other under immunization status

We refer the reader to the CDC web page at *https://www.cdc.gov/nchs/icd/icd10cm.htm* for additional details regarding the implementation of these new diagnosis codes.

As discussed in the proposed rule, we provided the MS–DRG assignments for the three diagnosis codes effective with discharges on and after April 1, 2022, consistent with our established process for assigning new diagnosis codes. Specifically, we review the predecessor diagnosis code and MS–DRG assignment most closely associated with the new diagnosis code, and consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, and the resources utilized for the specific condition/diagnosis. We note that this process does not automatically result in the new diagnosis code being assigned to the same MS–DRG as the predecessor code. The assignments for the previously listed diagnosis codes are reflected in Table 6A.—New Diagnosis Codes associated with the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. As with the other new diagnosis codes and MS–DRG assignments included in Table 6A in association with the proposed rule, we solicited public comments on the most appropriate MDC, MS–DRG, and severity level assignments for these codes for FY 2023, as well as any other options for the GROUPER logic.

We did not receive any comments opposing the MDC, MS–DRG, and severity level assignments for the listed codes and are therefore, finalizing the assignments as reflected in Table 6A.—New Diagnosis Codes in association with this final rule.

In addition, we noted in the proposed rule that CMS implemented nine new procedure codes describing the introduction or infusion of therapeutics, including vaccines for COVID–19prevention, into the ICD–10–PCS effective with discharges on and after April 1, 2022. The nine procedure codes listed in this section of this rule are designated as non-O.R. and do not affect any MDC or MS–DRG assignment as shown in the following table.

ICD-10-PCS Code	Description	O.R.	MDC	MS-DRG
XW013V7	Introduction of COVID-19 vaccine dose 3 into subcutaneous tissue, percutaneous approach, new technology group 7	N		
XW013W7	Introduction of COVID-19 vaccine booster into subcutaneous tissue, percutaneous approach, new technology group 7	N		
XW023V7	Introduction of COVID-19 vaccine dose 3 into muscle, percutaneous approach, new technology group 7	N		
XW023W7	Introduction of COVID-19 vaccine booster into muscle, percutaneous approach, new technology group 7	N		
XW023X7	Introduction of tixagevimab and cilgavimab monoclonal antibody into muscle, percutaneous approach, new technology group 7	N		
XW023Y7	Introduction of other new technology monoclonal antibody into muscle, percutaneous approach, new technology group 7	N		
XW0DXR7	Introduction of fostamatinib into mouth and pharynx, external approach, new technology group 7	N		
XW0G7R7	Introduction of fostamatinib into upper GI, via natural orartificial opening, new technology group 7	N		
XW0H7R7	Introduction of fostamatinib into lower GI, via natural or artificial opening, new technology group 7	N		

The ICD–10 MS–DRG assignment for cases reporting any one of the nine procedure codes is dependent on the reported principal diagnosis, any secondary diagnoses defined as a CC or MCC, procedures or services performed, age, sex, and discharge status. The nine procedure codes are reflected in Table 6B.—New Procedure Codes in association with the proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* As with the other new procedure codes and MS–DRG assignments included in Table 6B in association with the proposed rule, we solicited public comments on the most appropriate MDC, MS–DRG, and operating room status assignments for these codes for FY 2023, as well as any other options for the GROUPER logic.

We did not receive any comments opposing the MDC, MS–DRG, and operating room status assignments for the listed codes and are therefore, finalizing the assignments as reflected in Table 6B.—New Procedure Codes in association with this final rule.

In the proposed rule we also noted that Change Request (CR) 12578, Transmittal 11174, titled ''April 2022 Update to the Medicare Severity—Diagnosis Related Group (MS–DRG) Grouper and Medicare Code Editor (MCE) Version 39.1 for the International Classification of Diseases, Tenth Revision (ICD–10) Diagnosis Codes for 2019 Novel Coronavirus (COVID–19) Vaccination Status and ICD–10 Procedure Coding System (PCS) Codes for Introduction or Infusion of Therapeutics and Vaccines for COVID–19 Treatment'', was issued on January 14, 2022 (available via the internet on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r11174cp*) regarding the release of an updated version of the ICD–10 MS–DRG GROUPER and Medicare Code Editor software, Version 39.1, effective with discharges on and after April 1, 2022, reflecting the new diagnosis and procedure codes. The updated software, along with the updated ICD–10 MS–DRG V39.1 Definitions Manual and the Definitions of Medicare Code Edits V39.1 manual is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group

classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making those determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting were considered for an April 1 update if a strong and convincing case was made by the requestor during the Committee's public meeting. The request needed to identify the reason why a new code was needed in April for purposes of the new technology process. Meeting participants and those reviewing the Committee meeting materials were provided the opportunity to comment on the expedited request. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950) for further discussion of the implementation of this prior April 1 update for purposes of the new technology add-on payment process.

However, as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956), we adopted an April 1 implementation date, in addition to the annual October 1 update, beginning with April 1, 2022. We noted that the intent of this April 1 implementation date is to allow flexibility in the ICD–10 code update process. With this new April 1 update, CMS now uses the same process for consideration of all requests for an April 1 implementation date, including for purposes of the new technology add-on payment process (that is, the prior process for consideration of an April 1 implementation date only if a strong and convincing case was made by the requestor during the meeting no longer applies). We are continuing to use several aspects of our existing established process to implement new codes through the April 1 code update, which includes presenting proposals for April 1 consideration at the September ICD–10 Coordination and Maintenance Committee meeting, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments consistent with the new GROUPER release information. We note that under our established process, requestors indicate whether they are submitting their code request for consideration for an April 1 implementation date or an October 1 implementation date. The ICD–10 Coordination and Maintenance Committee makes efforts to accommodate the requested implementation date for each request submitted. However, the Committee determines which requests are to be presented for consideration for an April 1 implementation date or an October 1 implementation date. As discussed earlier in this section of the preamble of this final rule, there were code proposals presented for an expedited April 1, 2022 implementation at the September 14–15, 2021 Committee meetings that involved treatments related to the COVID–19 PHE. One of these code proposals was also in connection with a request for a new technology add-on payment application. Following the receipt of public comments, the code proposals were approved and finalized, therefore, there were new codes implemented April 1, 2022.

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, consistent with the process we outlined for the April 1 implementation date, we announced the new codes in November 2021 and provided the updated code files and ICD–10–CM Official Guidelines for Coding and Reporting in December 2021. On January 24, 2022 the **Federal Register** notice for the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee Meeting was published that includes the tentative agenda and identifies which topics are related to a new technology add-on payment application. By February 1, 2022 we made available the updated V39.1 ICD–10 MS–DRG Grouper software and related materials via the internet on CMS web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

Comment: A few commenters expressed concerns with the meeting process and timing for the implementation of new ICD–10–CM diagnosis codes by the CDC/NCHS. The commenters urged CMS to work with the CDC/NCHS on expediting the finalization of proposed new diagnosis codes in light of the option to implement codes on April 1. Another commenter expressed support for the ability of an April implementation and expedited diagnosis codes to improve reporting and health equity. The commenter requested that CMS consider utilizing this April 1 pathway to advance the Agency's and the health care system's equity goals, specifically for diagnosis codes that describe social and economic circumstances to more accurately reflect health care encounters and episodes of care while also contributing to reliability and validity of coded claims data.

Response: We thank the commenters for the feedback. As we have noted in prior rulemaking (85 FR 58556) the CDC/NCHS has lead responsibility for the ICD–10–CM diagnosis classification while CMS has lead responsibility for the ICD–10–PCS procedure classification. Each organization has their own established process in responding to requests for code updates, including when specific topics may appear on the agenda of an ICD–10 Coordination and Maintenance Committee meeting and the fiscal year in which code proposals are considered for implementation.

ICD–9–CM addendum and code title information is published on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum*. ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS website at: *https://www.cms.gov/medicare/coding/icd10*. CMS also sends electronic files containing all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can be found on the CDC website at: *https://www.cdc.gov/nchs/icd/icd10cm.htm*. Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the Coding Clinic for ICD–10. The AHA also distributes coding update information to publishers and software vendors.

In the proposed rule we noted that for FY 2022, there are currently 72,750 diagnosis codes and 78,229 procedure codes. We also noted that as displayed in Table 6A.—New Diagnosis Codes and in Table 6B.—New Procedure Codes associated with the proposed rule (and available via the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*), there were 1,176 new diagnosis codes and 45 new

procedure codes that had been finalized for FY 2023 at the time of the development of the proposed rule. As discussed in section II.D.14 of the preamble of this final rule, we are making available Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes and Table 6E.—Revised Diagnosis Code Titles via the internet on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps* in association with this final rule. As shown in Table 6B.—New Procedure Codes, there were procedure codes discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting that were not finalized in time to include in the proposed rule and are identified with an asterisk. We refer the reader to Table 6B.—New Procedure Codes associated with this final rule and available via the internet on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps* for the detailed list of these additional 286 new procedure codes. The addition of these 286 new procedure codes to the 45 procedure codes that had been finalized at the time of the development of the proposed rule results in a total of 331 (45 + 286 = 331) new procedure codes for FY 2023.

We also note, as reflected in Table 6C.—Invalid Diagnosis Codes and in Table 6D.—Invalid Procedure Codes, there are a total of 287 diagnosis codes and 64 procedure codes that will become invalid effective October 1, 2022. Based on these code updates, effective October 1, 2022, there are a total of 73,639 ICD–10–CM diagnosis codes and 78,496 ICD–10–PCS procedure codes for FY 2023 as shown in the following table.

FY 2022 ICD-10-CM	72,750 total codes	FY 2022 ICD-10-PCS	78,229 total codes
FY 2023 ICD-10-CM	1,176 additions	FY 2023 ICD-10-PCS	331 additions
FY 2023 ICD-10-CM	287 deletions	FY 2023 ICD-10-PCS	64 deletions
FY 2023 ICD-10-CM	**73,639 total codes**	**FY 2023 ICD-10-PCS**	**78,496 total codes**

As stated previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting. The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

18. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Changes for FY 2023

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, for FY 2023 we proposed not to add any MS–DRGs to the policy for replaced devices offered without cost or with a credit. We proposed to continue to include the existing MS–DRGs currently subject to the policy as displayed in the following table.

MDC	MS-DRG	MS-DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC
01	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
01	026	Craniotomy and Endovascular Intracranial Procedures with CC
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC
03	140	Major Head and Neck Procedures with MCC
03	141	Major Head and Neck Procedures with CC
03	142	Major Head and Neck Procedures without CC/MCC
05	215	Other Heart Assist System Implant
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC
05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC
05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC
05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC
05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC
05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
05	242	Permanent Cardiac Pacemaker Implant with MCC
05	243	Permanent Cardiac Pacemaker Implant with CC
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
05	245	AICD Generator Procedures
05	258	Cardiac Pacemaker Device Replacement with MCC
05	259	Cardiac Pacemaker Device Replacement without MCC
05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
05	265	AICD Lead Procedures
05	266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC
05	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC
05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
05	270	Other Major Cardiovascular Procedures with MCC
05	271	Other Major Cardiovascular Procedures with CC
05	272	Other Major Cardiovascular Procedures without CC/MCC
05	319	Other Endovascular Cardiac Valve Procedures with MCC
05	320	Other Endovascular Cardiac Valve Procedures without MCC
08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
08	466	Revision of Hip or Knee Replacement with MCC
08	467	Revision of Hip or Knee Replacement with CC
08	468	Revision of Hip or Knee Replacement without CC/MCC
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
08	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
08	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

We did not receive any public comments opposing our proposal to continue to include the existing MS–DRGs currently subject to the policy. Therefore, we are finalizing the list of MS–DRGs in the table included in the proposed rule and in this final rule that will be subject to the replaced devices offered without cost or with a credit policy effective October 1, 2022. The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be issued to providers in the form of a Change Request (CR).

19. Other Policy Issues

a. Comment Solicitation on Possible Mechanisms To Address Rare Diseases and Conditions Represented by Low Volumes Within the MS–DRG Structure

As discussed in section II.D.13.d of the preamble of the proposed rule and this final rule, we solicited public

comments involving how the reporting of certain diagnosis codes may improve our ability to recognize severity of illness, complexity of service, and utilization of resources under the MS–DRGs, as well as feedback on mechanisms to improve the reliability and validity of the coded data as part of an ongoing effort across CMS to evaluate and develop policies to reduce health disparities. In concert with that effort, as discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28195 through 28197) we also solicited comments to explore possible mechanisms through which we could address rare diseases and conditions that are represented by low volumes in our claims data.

We stated in the FY 2023 proposed rule that one subset of our beneficiary population for which we sought comment on potential issues related to patient access in the inpatient setting were patients diagnosed with rare diseases and conditions that are represented by low volumes in our claims data. We noted that the Orphan Drug Act (ODA) added section 526(a)(2)(B) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2)(B)), defining a rare disease or condition as ''any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.'' Most rare diseases, however, affect far fewer people. The Genetic and Rare Diseases Information Center (GARD), which was created in 2002 by the National Institutes of Health (NIH) Office of Rare Diseases Research, estimates that there are as many as 7,000 distinct rare diseases. Rare diseases, which can include genetic diseases, autoimmune conditions, some cancers, and uncommon infections, are highly diverse, may affect many organ systems and have wide variations in the rates and patterns of manifestations and progression.

The ODA created a process for the U.S. Food and Drug Administration (FDA) to identify a drug as a drug developed for the treatment of a rare disease or condition called ''orphan-drug designation''. The sponsor of a drug that has orphan drug designation may be eligible for certain financial incentives, such as tax credits and potentially seven years of market exclusivity after approval, all of which are intended to incentivize developing drugs for small numbers of patients. We stated that we heard from some interested parties, however, that there may be a number of barriers to providers in treating these patients with these orphan designated drugs in the Medicare hospital inpatient setting.

According to these interested parties, one significant barrier that continues to present challenges to manufacturers is accessing formulary coverage for potentially high cost therapeutics for rare diseases. These interested parties stated that hospitals utilize formularies for inpatient drugs as a cost-management tool that strongly incentivizes physicians to use on-formulary drugs over off-formulary drugs, whenever clinically appropriate to do so. A drug formulary is defined as a list of medications and continually updated related information, that represents the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease or promotion of health. It is often described as a list of medications routinely stocked by the health care system. These interested parties stated that although certain therapeutics can be associated with better outcomes for patients with rare diseases, the lack of access to hospital formularies represents a hurdle under the IPPS MS–DRGs. According to these interested parties, when Medicare reimbursement is insufficient to cover the costs of certain therapeutics that treat patients with rare diseases, a disincentive can be created in addressing these conditions.

For the purposes of the comment solicitation in the proposed rule, we described three selected requests we had received relating to the MS–DRG classification of rare diseases and conditions that are represented by low volumes in our claims data.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53311), the FY 2015 IPPS/LTCH PPS final rule (79 FR 49901) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41200), we discussed requests we received to revise the MS–DRG classification for cases of patients diagnosed with porphyria to recognize the resource requirements in caring for these patients, to ensure appropriate payment for these cases, and to preserve patient access to necessary treatments. Porphyria is defined as a group of rare disorders (''porphyrias'') that interfere with the production of hemoglobin that is needed for red blood cells. While some of these disorders are genetic (inborn) and others are acquired, they all result in the abnormal accumulation of hemoglobin building blocks, called porphyrins, which can be deposited in the tissues where they particularly interfere with the functioning of the nervous system and the skin. Treatment for patients suffering from disorders of porphyrin metabolism consists of an intravenous injection of Panhematin® (hemin for injection).

In the FY 2019 proposed rule, we stated our data analysis showed that cases reporting diagnosis code E80.21 (Acute intermittent (hepatic) porphyria) as the principal diagnosis in MS–DRG 642 (Inborn and Other Disorders of Metabolism) had higher average costs and longer average lengths of stay compared to the average costs and length of stay for all other cases in MS–DRG 642. However, after considering these findings in the context of the current MS–DRG structure, we stated that we were unable to identify an MS–DRG that would more closely parallel these cases with respect to average costs and length of stay that would also be clinically aligned. We further stated that our clinical advisors believed that, in the current MS–DRG structure, the clinical characteristics of patients in these cases are most closely aligned with the clinical characteristics of patients in all cases in MS–DRG 642. Moreover, given the small number of porphyria cases, we stated we did not believe there was justification for creating a new MS–DRG and did not propose to revise the MS–DRG classification for porphyria cases.

In response, some commenters described significant difficulties encountered by patients with acute porphyria attacks in obtaining Panhematin® when presenting to an inpatient hospital, which they attributed to the strong financial disincentives faced by facilities to treat these cases on an inpatient basis. The commenters stated that, based on the lower than expected average cost per case and longer than expected length of stay for acute porphyria attacks, it appeared that facilities were frequently not providing Panhematin® to patients in this condition, and instead attempting to provide symptom relief and transferring patients to an outpatient setting to receive the drug where they can be adequately paid. The commenters stated that this is in contrast to the standard of care for acute porphyria attacks and could result in devastating long-term health consequences.

In the FY 2019 final rule (83 FR 41200), as we have stated in prior rulemaking, we noted it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that involves increased costs. We further noted the MS–DRG system is a system of averages and it is expected that across

the diagnostic related groups that within certain groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. While we recognized the average costs of the small number of porphyria cases were greater than the average costs of the cases in MS–DRG 642 overall, we also noted that an averaged payment system depends on aggregation of similar cases with a range of costs, and that we seek to identify sufficiently large sets of claims data with a resource/cost similarity and clinical similarity in developing diagnostic-related groups rather than smaller subsets of diagnoses. We further stated that we were sensitive to the commenters' concerns about access to treatment for beneficiaries who have been diagnosed with this condition and we would continue to explore mechanisms through which to address rare diseases and low volume DRGs.

Similarly, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44869), we discussed a request we received to review potential access issues in the inpatient setting for the administration of ANDEXXA®. ANDEXXA® (coagulation factor Xa (recombinant), inactivated-zhzo) is a recombinant decoy protein that rapidly reverses the anticoagulant effects of two direct oral anticoagulants, apixaban and rivaroxaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding in indications such as intracranial hemorrhages (ICHs) and gastrointestinal bleeds (GIBs). We noted that while our data findings demonstrated the average costs for the cases reporting the intravenous administration of ANDEXXA® were higher when compared to all cases in their respective MS–DRG, these cases represented a very small percentage of the total number of cases reported in those MS–DRGs. We stated we were unable to identify another MS–DRG that would be a more appropriate MS–DRG assignment for these cases based on the indication for this therapeutic drug. We also stated that while we were sensitive to the requestors' concerns about continued access to treatment for beneficiaries who require the reversal of anticoagulation due to life-threatening or uncontrolled bleeding, we indicated additional time was needed to explore options and other mechanisms through which to address low volume, high-cost drugs outside of the MS–DRGs.

Lastly, in the proposed rule, we discussed a request we received to reconsider how cases reporting the administration of Zulresso® (brexanolone) are recognized for payment under the ICD–10 MS–DRGs in an effort to improve access to treatment for maternal mental health. On March 19, 2019 Zulresso® (brexanolone) became the first Food and Drug Administration (FDA) approved drug, specifically for postpartum depression (PPD) in adults. According to the requestor, PPD is one of the most common complications during and after pregnancy. The requestor stated PPD is a serious but manageable disorder and that with early treatment, the life of the mother, baby, and the entire family could be positively impacted. The requestor indicated it shares CMS's goals of addressing disparities in access to care, and urged CMS to take additional steps to address inequities in women's health by permitting separate payment for Zulresso® (brexanolone), in addition to the MS–DRG payment.

As discussed in the proposed rule, effective with discharges on and after October 1, 2020, cases reporting the administration of Zulresso® in the inpatient setting are identified by ICD–10–PCS procedure codes XW03306 (Introduction of brexanolone into peripheral vein, percutaneous approach, new technology group 6) or XW04306 (Introduction of brexanolone into central vein, percutaneous approach, new technology group 6). These procedure codes are designated as non-O. R. procedures and do not affect the MS–DRG assignment when reported on an inpatient claim. We noted that an application for new technology add-on payment for Zulresso® (brexanolone) was discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32672 through 32676) and was not approved, as discussed in the final rule (85 FR 58709 through 58715).

We stated we analyzed claims from the September 2021 update of the FY 2021 MedPAR file for cases reporting the administration of Zulresso® (brexanolone). Our analysis of the claims data identified only one case reporting the administration of Zulresso® (brexanolone) in MS–DRG 870 (Septicemia or Severe Sepsis with MV >96 Hours) with an average length of stay of 22 days and average costs of $67,812. For all cases in MS–DRG 870, the average costs are $55,459 and the average length of stay is 15.9 days. We stated that while the average length of stay for the case reporting the administration of Zulresso® (brexanolone) was greater (22 days versus 15.9 days) and the average costs were higher ($67,812 versus $55,459), than all cases in MS–DRG 870 it was unclear if treatment with Zulresso® (brexanolone) was the underlying reason for these factors, given that the MS–DRG assigned is for sepsis and it is not uncommon for sepsis patients to have multiple co-morbidities and intensive treatment strategies to address this severe, often life threatening condition.

We stated we appreciated the requestor's interest in sharing CMS's goal of advancing women's health, however, we noted that the population in which Zulresso® (brexanolone) is indicated generally does not include our inpatient Medicare population. As we have stated in prior rulemaking, (83 FR 41210), we have not adopted the same approach to refine the maternity and newborn MS–DRGs because of the extremely low volume of Medicare patients there are in these MS–DRGs. When there is not a high volume of these cases (for example, maternity and newborn) represented in the Medicare data, we generally advise that other payers should develop DRGs to address the needs of their patients. We stated we believed the same would apply with respect to administration of Zulresso® (brexanolone) for which, as noted, we identified only one case in the FY 2021 MedPAR file.

As discussed in prior rulemaking, the MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. Rare diseases and conditions that are represented by low volumes in our claims data however, pose a unique challenge to this methodology as these conditions by definition affect small subsets of the population. In the proposed rule, we stated that it has been difficult to identify other MS–DRGs that would be more appropriate MS–DRG assignments for these rare conditions based on the wide variance in the clinical characteristics and utilization of resources for each condition, depending on the diagnosis. Creating a new MS–DRG for these conditions as a distinct ''related'' group is also challenging for the same reasons.

As previously noted, we generally seek to identify sufficiently large sets of claims data with a resource/cost similarity and clinical similarity in developing diagnostic-related groups rather than smaller subsets. In the proposed rule, we stated that we have been concerned that basing MS–DRG reclassification decisions on small numbers of cases could lead to complexities in establishing the relative payment weights for the MS–DRGs because several expensive cases could impact the overall relative payment weight. Having larger clinical cohesive groups within an MS–DRG provides greater stability and thus predictability

for hospitals for annual updates to the relative payment weights.

As also previously noted, the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. However, as noted, cases involving treatment of rare diseases may involve more resource use than other cases in their respective MS–DRG. Section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs, however we solicited feedback on other mechanisms we could explore through which we can address concerns relating to payment for patients with rare diseases and conditions that are represented by low volumes in our claims data. We stated we were also interested in receiving comments on other meaningful ways in which we might potentially improve access to treatment for postpartum depression in certain populations, including through activities pursuant to Vice President Harris's Call to Action to Reduce Maternal Mortality and Morbidity.[28]

To inform decision making, we stated we were also looking for feedback on how to mitigate any unintended negative payment impacts to providers serving patients with rare diseases or conditions that are represented by low volumes in our claims data. In particular, we stated we were interested in hearing the perspectives of large urban hospitals, rural hospitals, and other hospital types in regard to their experience. We also sought comments on how factors such as hospital size and type might impact a hospital's ability to develop protocols to better address these conditions. We stated we would take commenters' feedback into consideration in future policy development.

Comment: Many commenters stated they appreciated CMS' attention and the acknowledgment of the challenging nature of rare diseases as part of a reporting and payment structure. Commenters also expressed that they fully support the Administration's initiatives that champion policies to improve maternal health and equity, especially as it relates to PPD. Most commenters provided recommendations and suggested CMS explore mechanisms such as—

- Creating a ''permanent'' payment methodology approach which combines the MS–DRG ''fixed price'' with continued partial payment for the actual cost of treatment per stay;
- Creating new MS–DRGs for certain low-volume therapies or for orphan conditions with more flexible cost outlier funding;
- Creating new MS–DRG categories to ensure access to rapidly expanding transformative therapies like cell and gene therapies;
- Creating a new enhanced new technology add-on payment-like pathway that establishes separate payment for low volume high-cost drugs;
- Reimbursing hospitals for orphan drugs based on the Average Sales Price (ASP) as published in the HOPD Addendum B file using the same authority that the Agency relied on to make the recent COVID–19 payment adjustments;
- Carving-out ''clinical trial'' inpatient stays to ensure that the MS–DRG payment rate is not adversely impacted by facility-reported costs that do not include acquisition costs;
- Exploring databases outside of the MedPAR to obtain claims data for inclusion analysis;
- Creating a rare disease diagnosis code designation, similar to the complication or comorbidity (CC) and major complication or comorbidity (MCC) severity designations;
- Establishing a central formulary to provide high cost drugs for rare conditions instead of utilizing individual hospital pharmacy formularies to ease burdens of carrying high cost drugs on rural and smaller hospitals, as drug transport can potentially be cheaper then patient transport;
- Waiving the 500 case threshold when deciding whether an MS–DRG change should be proposed.

Specifically, in discussing how cases reporting the administration of Zulresso® (brexanolone) are recognized for payment, commenters stated that if Medicare commits to creating MS–DRGs around the Medicare population giving birth, the impacts of this progress would have far-reaching effects beyond Medicare beneficiaries as it will serve as the foundation for commercial and Medicaid payments.

Response: We appreciate the input provided by commenters in response to this request for information and we thank commenters for the acknowledgment of the challenges rare diseases or conditions that are represented by low volumes present as part of a reporting and reimbursement structure. We thank the commenters for their support and consideration of these issues. We will take the comments received in response to the solicitation into consideration as we continue to explore mechanisms to address concerns relating to payment for patients with rare diseases and conditions that are represented by low volumes in our claims data.

20. Out of Scope Public Comments Received

We received public comments on MS–DRG related issues that were outside the scope of the proposals included in the FY 2023 IPPS/LTCH PPS proposed rule. Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule. As stated in section II.D.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classifications to submit these comments no later than October 20, 2022 via the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home* so that they can be considered for possible inclusion in the annual proposed rule. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

II. Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

E. Recalibration of the FY 2023 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

Consistent with our established policy, in developing the MS–DRG relative weights for FY 2023, we proposed to use two data sources: claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2021 MedPAR data used in this final rule include discharges occurring on October 1, 2020, through September 30, 2021, based on bills received by CMS through March 31, 2022, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS).

The FY 2021 MedPAR file used in calculating the relative weights includes data for approximately 7,444,003

[28] *Available at: https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/.*

Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the March 2022 update of the FY 2021 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2023 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the FY 2023 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2021 MedPAR claims data, grouped through the ICD–10 version of the FY 2023 GROUPER (Version 40).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. In general, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, for this final rule, we used the March 2022 update of the FY 2020 HCRIS for calculating the FY 2023 cost-based relative weights. Consistent with our historical practice, for this FY 2023 final rule, we are providing the version of the HCRIS from which we calculated these 19 CCRs on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. Click on the link on the left side of the screen titled ''FY 2023 IPPS Final Rule Home Page'' or ''Acute Inpatient Files for Download.''

2. Methodology for Calculation of the Relative Weights

a. General

We calculated the FY 2023 relative weights based on 19 CCRs. The methodology we proposed to use to calculate the FY 2023 MS–DRG cost-based relative weights based on claims data in the FY 2021 MedPAR file and data from the FY 2020 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the FY 2023 MS–DRG classifications discussed in sections II.B. and II.D. of the preamble of this final rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2021 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis.

Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

Section 108 of the Further Consolidated Appropriations Act, 2020 provides that, for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant shall be paid on a reasonable cost basis. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of the reasonable cost basis payment for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842). For FY 2022 and subsequent years, we subtract the hematopoietic stem cell acquisition charges from the total charges on each transplant bill that showed hematopoietic stem cell acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 93.0 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower

severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI Initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The participation of hospitals in the BPCI initiative concluded on September 30, 2018. The participation of hospitals in the BPCI Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 1115A of the Act, is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: as a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/bpci-advanced/*. Consistent with our policy for FY 2022, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2023, we continue to believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted previously, these hospitals are still receiving IPPS payments under section 1886(d) of the Act. Consistent with the FY 2022 IPPS/LTCH PPS final rule, we also proposed to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2020 cost report data.

The 19 cost centers that we used in the relative weight calculation are shown in a supplemental data file, Cost Center HCRIS Lines Supplemental Data File, posted via the internet on the CMS website for this final rule and available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs. In the FY 2023 IPPS/LTCH PPS proposed rule, we stated that if we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy.

Comment: A commenter requested that CMS create a dedicated cost center line for cell and gene therapy product cost information, which would enable the agency to create a 20th cost center that is separate from the drugs/pharmacy cost center.

Response: We appreciate the commenter's request regarding the creation of new cost centers for cell and gene therapy product cost information and may consider this request in connection with future rulemaking.

After consideration of the comment received, we are finalizing our proposal to use the 19 national cost center CCRs to calculate the relative weights for FY 2023.

Consistent with historical practice, we account for rare situations of non-monotonicity in a base MS–DRG and its severity levels, where the mean cost in the higher severity level is less than the mean cost in the lower severity level, in determining the relative weights for the different severity levels. If there are initially non-monotonic relative weights in the same base DRG and its severity levels, then we combine the cases that group to the specific non-monotonic MS–DRGs for purposes of relative weight calculations. For example, if there are two non-monotonic MS–DRGs, combining the cases across those two MS–DRGs results in the same relative weight for both MS–DRGs. The relative weight calculated using the combined cases for those severity levels is monotonic, effectively removing any non-monotonicity with the base DRG and its severity levels. For this FY 2023 final rule, this calculation was applied to address non-monotonicity for cases that grouped to MS–DRG 793 and MS–DRG 794. In the supplemental file titled AOR/BOR File, we include statistics for the affected MS–DRGs both separately and with cases combined.

We invited public comments on our proposals related to recalibration of the proposed FY 2023 relative weights and the changes in the relative weights from FY 2022.

Comment: A commenter requested that CMS study whether it might be appropriate to define the labor portion individually for each of the 19 cost centers and only standardize that portion, particularly if doing so improves the explanatory power of all MS–DRGs. This commenter requested that CMS conduct this study in collaboration with stakeholders and release this analysis in future rulemaking.

Response: We appreciate the commenter's request that CMS study the appropriateness of defining the labor portion individually for each of the 19 cost centers and standardizing only that portion, and we may consider this request in connection with future rulemaking.

After consideration of the comment received, we are finalizing our proposals related to the recalibration of the FY 2023 relative weights. We summarize and respond to comments relating to the methodology for calculating the relative weight for MS–DRG 018 in the next section of this final rule.

b. Relative Weight Calculation for MS–DRG 018

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58599 through 58600), we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3. Effective for FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106). We refer the reader to section II.D.2. of this final rule for discussion of the agenda items for the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting relating to new procedure codes to describe the administration of a CAR T-cell or another type of gene or cellular therapy product, as well as our established process for determining the MS–DRG assignment for codes approved at the March meeting.

For MS–DRG 018, we include a modification to our existing relative weight methodology to ensure that the relative weight for MS–DRG 018 appropriately reflects the relative resources required for providing CAR T-cell and non-CAR T-cell therapies and other immunotherapies outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS–DRGs. For cases that group to MS–DRG 018, we do not include claims determined to be clinical trial claims that group to MS–DRG 018 when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that: (a) when the CAR T-cell, non-CAR T-cell or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, we include the claim when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data; and (b) when there is expanded access use of the CAR T-cell, non-CAR T-cell or other immunotherapy product, these cases will not be included when calculating the average cost for new MS DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). We also calculate an adjustment to account for the CAR T-cell, non-CAR T-cell and other immunotherapy cases determined to be clinical trial cases, as described later in this final rule and include revenue center 891 in our calculation of standardized drug charges for MS–DRG 018. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of our modifications to the relative weight calculation for MS–DRG 018.

We proposed to continue to use the same process to identify clinical trial claims in the FY 2021 MedPAR for purposes of calculating the FY 2023 relative weights. We continue to use the proxy of standardized drug charges of less than $373,000, which was the average sales price of KYMRIAH and YESCARTA, which are the two CAR T-cell biological products in the FY 2021 MedPAR data used for this final rule. (As previously noted, effective beginning FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).) Using the same methodology from the FY 2021 IPPS/LTCH PPS final rule, we proposed to apply an adjustment to account for the CAR T cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs:

- Calculate the average cost for cases to be assigned to MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for all other cases to be assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply the adjustor calculated in step 3 to the cases identified in step 1 as clinical trial cases, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS–DRGs.

Additionally, we are continuing our finalized methodology for calculating this payment adjustment, such that: (a) when the CAR T-cell, non-CAR T-cell or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases; and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases. However, we continue to believe to the best of our knowledge there are no claims in the historical data (FY 2021 MedPAR) used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000.

Applying this previously finalized methodology, based on the December 2021 update of the FY 2021 MedPAR file used for the proposed rule, we estimated that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($61,356) were 20 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($299,460). Accordingly, as we did for FY 2022, we proposed to adjust the transfer-adjusted case count for MS–DRG 018 by applying the proposed adjustor of 0.20 to the applicable clinical trial and expanded access use immunotherapy cases, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of the proposed rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case was adjusted by 0.20. As we did for FY 2022, we applied this same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations. We also proposed to update the value of the adjustor based on more recent data for the final rule.

Comment: Several commenters were supportive of CMS' continued use of MS–DRG 018 as it is currently

structured, including the identification and exclusion of CAR T-cell clinical trial and expanded access use cases assigned to MS–DRG 018. Commenters stated that the stability of MS–DRG 018 will help ensure beneficiary access to CAR T-cell therapy services. One commenter stated that analysis of CAR T-cell claims data from FY 2021 through the first quarter of FY 2022 shows significant improvement in patient access to CAR T. Another commenter requested that CMS reevaluate the clinical trial threshold annually as acquisition costs increase and additional therapies are introduced to MS–DRG 018.

Other commenters stated that they were concerned with what they stated were Medicare under-reimbursements for CAR T-cell technology, especially given the array of resources used to treat patients undergoing these complex, novel cell therapies and the adverse impact inadequate reimbursement has on beneficiary access. A commenter stated that payment for MS–DRG 018 is almost 30 percent below the cost of CAR T-cell cases and does not cover the cost of the therapy itself. A commenter recommended that CMS cover the full cost of the CAR T-cell therapy, while another commenter requested that CMS implement a policy solution that will ensure providers recoup at least the invoice cost of the CAR T-cell product. The commenter referenced prior comments about options for such policy solutions. Some commenters stated that the increase in the fixed-loss threshold makes it even more difficult to obtain adequate reimbursement. A commenter requested that CMS closely monitor reimbursement rates for CAR T-cell therapies to ensure that hospital facilities can continue to provide access to these treatments.

Response: We appreciate the support and feedback on our proposal to use the same ratesetting methodology for MS–DRG 018 in FY 2023 as we have in prior years. With regard to the commenter who requested that CMS reevaluate the clinical trial threshold annually, we note that we continue to monitor the data and may engage further with the public and consider this comment in connection with future rulemaking. With regard to the comments that the MS–DRG relative weight for MS–DRG 018 is inadequate and does not result in payment that fully covers the hospital resource costs, we refer readers to the FY 2022 IPPS/LTCH final rule (86 FR 44965) where we responded to similar comments.

Comment: A commenter stated that they understand that outliers are removed in the development of MS–DRGs so that they do not skew the results. The commenter found that in the calculation of the relative weights, MS–DRG 018 has the highest percent of cases removed as statistical outliers. The commenter stated the removal of these cases resulted in a lower standardized cost per inpatient stay. Another commenter requested that CMS monitor the impact that the removal of these statistical outliers has on MS–DRG 018 and other low volume services.

Response: We examined the cases referenced by the commenter that were removed as statistical outliers in the FY 2021 MedPAR claims data. We found that these cases had very high charges and very short lengths of stay, with daily charges in excess of $1.2 million relative to the average daily charge of $114,000 for MS–DRG 018. As described earlier in this section, our standard method to identify and remove statistical outliers excludes cases with total charges and total daily charges that are beyond 3 standard deviations from the geometric mean of the log distribution of both average total charges and average total daily charges of the respective MS–DRG. As described in section III.B.4.b. of the preamble of this final rule with respect to the MS–LTC–DRGs, statistical outliers are removed because we believe that they may represent aberrations in the data that distort the measure of average resource use. For this reason, we believe that the cases identified by the commenters are appropriately excluded as outliers, as their inclusion could distort the measure of average resource use for MS–DRG 018. We will continue to monitor the removal of statistical outliers in calculating the relative weights for MS–DRG 018.

Comment: A commenter recommended that CMS establish a new, alternative payment model under CMMI for gene and cell therapies, outside of the constraints of the IPPS. The commenter stated that this would provide a clearer path to coverage and payment policy that can improve patient access. Another commenter stated that some exceptions to the standard IPPS process are and will continue to be needed to allow hospitals to make lifesaving therapies available at launch to Medicare beneficiaries as soon as possible.

Response: We believe that is premature to make structural changes to the IPPS at this time to pay for gene and cell therapies. We may consider these comments for future rulemaking as we gain more experience in paying for these therapies under the IPPS.

Comment: Some commenters expressed concern that CMS mapped revenue codes 087X for cell and gene therapy services furnished by hospital staff to the drug cost group. One commenter stated that the NUBC definition states this revenue code series is for ''[c]harges for procedures performed by staff for the acquisition and infusion/injection of genetically modified cells''. The commenter stated that there is no standard cost center to report staff expense associated with the 087X series, but that it is inappropriate to assign the revenue for cell collection and processing services employed by hospital nursing and laboratory staff to the drug/pharmacy cost center. The commenter stated that if CMS finalizes this proposed mapping, it will be inconsistent with the mapping of revenues and expenses that hospitals are required to adhere to in their cost reports. A commenter suggested that CMS should revise the mapping of the 087X revenue codes to more closely reflect the departments where the staff expenses are recorded on the cost report. Commenters suggested that CMS map revenue codes 0871 and 0874 to the ''other'' cost center and 0872 and 0873 to the laboratory cost center. A commenter requested that CMS allow providers to bill for cell collection and cell processing services on the day that the services are rendered rather than adding them to the inpatient claim. The commenter stated that these are separate from the manufacturing process and are not included in the acquisition cost of the product.

Response: We disagree with the commenters that revenue center codes 087X are inappropriately mapped to the drug cost center. Cell collection and processing activities are part of the steps required to manufacture the drug, and thus assignment to the drug cost center accurately allocates these costs. Given this, we believe it is appropriate to apply the drug CCR to these charges for purposes of calculating the relative weights. With respect to the commenter who indicated that finalizing the proposed assignment of the 087X codes would be inconsistent with the mapping of revenues and expenses hospitals are required to adhere to in their cost reports, it is unclear to us what requirements are being referred to. With respect to the commenter who requested that CMS allow separate billing for the cell collection and processing services, as we discussed in the CY 2022 OPPS final rule (86 FR 63550), CMS does not believe that separate payment is necessary for the various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step

used to manufacture a drug or biological product.

Comment: A commenter requested that CMS consider allowing hospitals to use expanded access condition code 90 instead of the remarks field, which would remove a layer of manual work required by the MACs, which would decrease the opportunity for errors.

Response: We agree with the commenter that the availability of condition code 90 obviates the need for the use of the remarks field to identify expanded access claims that group to MS–DRG 018 for the purposes of applying the clinical trial adjustment. Effective October 1, 2022, providers should submit condition code 90 to identify expanded access claims that group to MS–DRG 018, rather than the remarks field. The MACs will no longer flag cases as expanded access claims based on information submitted in the remarks field for claims submitted on or after October 1, 2022.

Comment: A commenter requested that CMS provide additional clarification on the agency's methodology to develop the relative weight for both MS–DRG 018 and its overall ratesetting methodology. This commenter requested that CMS describe the order of operations, including step-by-step instructions of when to exclude certain types of claims. This commenter also requested that CMS clarify whether the agency trims claims first, and then sets aside clinical trial cases, or sets aside clinical trial claims and claims with less than $373,000 and then performs trimming.

Response: In response to the commenter's specific question regarding when CMS removes clinical trial cases from MS–DRG 018, the trims to remove clinical trial cases from MS–DRG 018 are done prior to the elimination of statistical outliers. In response to the commenter's request that we clarify our relative weight methodology more generally, we note that in each year's IPPS/LTCH PPS proposed and final rules, we include a section describing the recalibration of the MS–DRG relative weights and methodology for calculating the relative weights. We refer readers to sections II.E.1. and E.2.a. of the preamble of this final rule, in which we describe the trims we apply to the MedPAR claims to exclude non-IPPS claims, and provide a detailed description of the methodology we use to calculate the relative weights. The order that the trims are applied is consistent with the narrative description of our methodology. In addition, since the creation of MS–DRG 018, we have provided a description of the calculation of the relative weight for MS–DRG 018, including a step-by-step calculation of the CAR T-cell clinical trial adjustment factor, as set forth earlier in this section.

We also note that some commenters requested additional clarifications regarding billing instructions for CAR T-cell therapies, such as appropriate CAR T-cell billing and charges. We do not believe changes to billing guidance are needed at this time but will take these comments into consideration when developing policies and program requirements for future years for CAR T-cell therapy policy.

After consideration of the public comments we received, we are finalizing our proposals regarding the calculation of the relative weight for MS–DRG 018. Applying this finalized methodology, based on the March 2022 update of the FY 2021 MedPAR file used for this final rule, we estimated that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($61,540) were 21 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($293,546). Accordingly, as we did for FY 2022, we are finalizing our proposal to adjust the transfer-adjusted case count for MS–DRG 018 by applying the adjustor of 0.21 to the applicable clinical trial and expanded access use immunotherapy cases, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of this final rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case was adjusted by 0.21. As we did for FY 2022, we are applying this same adjustor for the applicable cases that group to MS DRG 018 for purposes of budget neutrality and outlier simulations.

c. Averaging of Relative Weights for FY 2023

In section I.F. of the proposed rule and this final rule, we discuss our proposal to use the FY 2021 MedPAR data for purposes of FY 2023 IPPS ratesetting, with certain proposed modifications to our usual methodologies, including an averaging approach for calculating the FY 2023 relative weights. As discussed in the proposed rule, we observed that COVID–19 cases were impacting the relative weights as calculated using the FY 2021 claims data for a few COVID–19-related MS–DRGs. For example, for MS–DRG 870 (Septicemia or Severe Sepsis with MV >96 hours), the relative weight calculated using the FY 2021 MedPAR data was approximately 9 percent higher than the relative weight calculated excluding the COVID–19 cases in the FY 2021 data. As also discussed in that section, we believe it is reasonable to assume that there will be fewer COVID–19 hospitalizations among Medicare beneficiaries in FY 2023 than there were in FY 2021. However, we cannot know the precise number of COVID–19 hospitalizations among Medicare beneficiaries in FY 2023. To account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries as compared to FY 2021, we proposed to determine the MS–DRG relative weights for FY 2023 by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data, as described in greater detail in this section. Given the uncertainty in the number of COVID–19 hospitalizations in FY 2023, we proposed to use 50 percent of the relative weights calculated using all applicable cases in the FY 2021 claims data and 50 percent of the relative weights calculated without the COVID–19 cases in the FY 2021 claims data. We stated that we believe this proposed approach would appropriately reduce, but not remove entirely, the effect of COVID–19 cases on the relative weight calculations, consistent with our expectation that Medicare inpatient hospitalizations for COVID–19 will continue in FY 2023 at a lower level as compared to FY 2021. By averaging the relative weights in this manner, we stated that we believe the result would reflect a reasonable estimation of the case mix for FY 2023 based on the information available at the time, as discussed in section I.F. of the preamble to the proposed rule and this final rule, and more accurately estimate the relative resource use for the cases treated in FY 2023 than if we were to calculate the proposed relative weights based on 100 percent of the relative weights as calculated for all applicable cases in the FY 2021 data. For the proposed rule, our proposed calculation was as follows:

- *Step 1:* Calculate a set of relative weights using all applicable cases in the December 2021 update of the FY 2021 MedPAR data, using the methodology as described earlier in this section, and then applying a normalization adjustment factor as described later in this section.
- *Step 2:* Calculate a set of relative weights using the December 2021 update of the FY 2021 MedPAR data excluding cases with a principal or secondary diagnosis of COVID–19 (ICD–10–CM diagnosis code U07.1), and

otherwise using the methodology as described earlier in this section, and then applying a normalization adjustment factor as described later in this section.

- *Step 3:* Average the results of step 1 and step 2 to calculate a set of averaged relative weights, geometric mean length of stays, and arithmetic mean length of stays.
- *Step 4:* Calculate the proposed FY 2023 relative weights by applying an additional normalization factor to these averaged relative weights. This additional normalization factor is necessary to ensure that the average case weight as calculated in step 3 of this proposed averaging methodology for recalibration of the FY 2023 relative weights is equal to the average case weight before recalibration. We note that this factor is very close to 1 and is described later in this section.

We noted that in Step 5 of this proposed calculation, we applied the proposed 10 percent cap to the relative weights for those MS–DRGs for which the relative weight as calculated in Step 4 would otherwise have declined by more than 10 percent from the FY 2022 relative weight, as discussed more fully later in this section. We also noted that we intended to update this calculation for the final rule using the March 2022 update of the FY 2021 MedPAR file.

We set forth the proposed relative weights, geometric mean length of stay, and average length of stay as calculated using this proposed methodology in Table 5 associated with the proposed rule, which is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. We also made available the relative weights, geometric mean length of stay, and average length of stay as calculated in steps 1 and 2 of this proposed methodology on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

Comment: Several commenters supported our proposal to average the relative weights calculated with and without COVID–19 cases, stating that this would more accurately account for the anticipated change in case mix as COVID–19 cases decline.

Another commenter supported an alternative MS–DRG relative weight methodology, but stated that the proposed methodology does not do enough to control for variability. This commenter requested that CMS use FY 2019 claims or some other alternate blend using the FY 2021 claims to establish the FY 2023 relative weights.

Some commenters expressed concern about policies that may limit the reimbursement for COVID–19 cases. A commenter suggested increasing the relative weights for the MS–DRGs that have documented COVID–19 cases, but recommended that CMS consider a process to differentiate patients who test asymptomatically for COVID–19 from those whose COVID–19 infection is causing clinical symptoms to worsen. The commenter stated that this approach would better target the more resource intensive beneficiaries without artificially constraining reimbursement for their care.

Response: We appreciate commenters' support for and feedback on our proposal. However, we disagree that we should blend other data sources or take additional steps to control for variability in the FY 2023 relative weights. As we stated in the FY 2023 IPPS/LTCH PPS proposed rule, we cannot know the precise number of COVID–19 hospitalizations among Medicare beneficiaries as compared to FY 2021. Our proposal to average the relative weights is intended to reflect a reasonable estimation of the case mix for FY 2023 based on the information available at this time, not to completely remove all variability in the FY 2023 relative weights. Our proposed methodology uses the FY 2021 MedPAR claims file to determine the FY 2023 relative weights, as the most recent available data during the period of the COVID–19 PHE, with modifications to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals as compared to FY 2021. As discussed in section I.F. of this final rule, after reviewing the latest CDC hospitalization data available at this time, we continue to believe that it is reasonable to assume that some Medicare beneficiaries will be hospitalized with COVID–19 at IPPS hospitals in FY 2023, but that there will be fewer COVID 19 hospitalizations as compared to FY 2021. With respect to the commenters' concerns about policies that may limit reimbursement for COVID–19 cases, we note that the majority of cases that include a diagnosis of COVID–19 (ICD–10–CM diagnosis code U07.1) group to MS–DRGs 177 and 871, and that the relative weights calculated using the proposed averaging methodology for FY 2023 are higher than the FY 2022 relative weights for these MS–DRGs. For MS–DRG 177, the relative weight calculated using the proposed averaging approach is also higher than the relative weight calculated using all applicable cases in the FY 2021 MedPAR file. For MS–DRG 871, while the relative weight calculated using the proposed averaging approach is lower than the relative weight calculated using all applicable cases in the FY 2021 MedPAR file, it is still an increase as compared to the relative weight for FY 2022. Moreover, as previously discussed, we believe that use of the proposed averaging methodology would provide a more accurate estimate of relative resource use for FY 2023 than if we were to calculate the proposed relative weights using all applicable cases in the FY 2021 data, and is consistent with our expectation, based on the information available at this time, that Medicare inpatient hospitalizations for COVID–19 will continue in FY 2023 at a lower level as compared to FY 2021. With regard to the suggestion about differentiating between symptomatic and asymptomatic COVID–19 cases, at this time we do not believe it is operationally feasible to make such a distinction given that separate coding does not exist to differentiate these cases. We may consider this suggestion in connection with future rulemaking.

After consideration of comments received, we are finalizing our proposal to determine the FY 2023 MS–DRG relative weights by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data, as previously described. As previously discussed, for this final rule, we are using the March 2022 update of the FY 2021 MedPAR file to determine the final relative weights for FY 2023. The relative weights, geometric mean length of stay, and average length of stay as calculated using this methodology are set forth in Table 5 associated with this final rule, which is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. We are also making available the relative weights, geometric mean length of stay, and average length of stay as calculated in steps 1 and 2 of this methodology on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

d. Cap for Relative Weight Reductions

In the FY 2018 IPPS/LTCH PPS final rule, we summarized comments we had received requesting a transition period for substantial reductions in relative weights in order to facilitate payment stability. Specifically, some commenters requested that CMS establish a cap on the decline in a relative weight from FY 2017 to FY 2018, or a phase-in or multi-year transition period in cases of substantial fluctuation of payment rates (82 FR 38103).

After consideration of these comments, and for the reasons discussed in the FY 2018 final rule, we adopted a temporary one-time measure for FY 2018 for MS–DRGs where the relative weight would have declined by more than 20 percent from the FY 2017 relative weight, consistent with our general authority to assign and update appropriate weighting factors under sections 1886(d)(4)(B) and (C) of the Act (82 FR 38103). Specifically, for these MS–DRGs, the relative weight for FY 2018 was set at 80 percent of the FY 2017 relative weight. In the FY 2019 IPPS/LTCH PPS final rule, in response to similar comments, we adopted a temporary one-time measure for FY 2019 for an MS–DRG where the FY 2018 relative weight declined by 20 percent from the FY 2017 relative weight and the FY 2019 relative weight would have declined by 20 percent or more from the FY 2018 relative weight (83 FR 41273). Specifically, for an MS–DRG meeting this criterion, we set the FY 2019 relative weight equal to the FY 2018 relative weight. In the FY 2020 IPPS/LTCH PPS final rule, in response to similar comments, we adopted a temporary one-time measure for FY 2020 for an MS–DRG where the FY 2018 relative weight declined by 20 percent from the FY 2017 relative weight and the FY 2020 relative weight would have declined by 20 percent or more from the FY 2019 relative weight, which was maintained at the FY 2018 relative weight (84 FR 42167). Specifically, for an MS–DRG meeting this criterion, we set the FY 2020 relative weight equal to the FY 2019 relative weight, which was in turn set equal to the FY 2018 relative weight.

In the FY 2021 IPPS/LTCH PPS proposed rule, we noted the one-time measure adopted for FY 2020 and sought comment on whether we should consider a similar policy for FY 2021, or an alternative approach such as averaging the FY 2020 relative weight and the otherwise applicable FY 2021 relative weight for MS–DRG 215, which was the only MS–DRG impacted by the FY 2020 policy setting the FY 2020 relative weight equal to the FY 2019 relative weight. Commenters generally supported either setting the FY 2021 weight for MS–DRG 215 equal to the FY 2020 relative weight or an averaging approach. Some commenters requested that CMS consider such an approach when the relative weight for an MS–DRG is drastically reduced in a given year, particularly when it follows a significant decline in prior years. After consideration of comments received, and for the reasons discussed in the FY 2021 final rule, we set the FY 2021 relative weight for MS–DRG 215 equal to the average of the FY 2020 relative weight and the otherwise applicable FY 2021 weight. With regard to the concerns raised about other MS–DRGs with significant reductions relative to FY 2020, we noted that these other MS–DRGs were low volume in our claims data, and therefore typically experience a greater degree of year-to-year variation. We acknowledged the longstanding concerns related to low volume MS–DRGs and stated that we would take into consideration the unique issues relating to such MS–DRGs and the stability of their weights for future rulemaking.

As we stated in the FY 2023 IPPS/LTCH PPS proposed rule, we have continued to consider the comments we received in response to prior rulemaking recommending that CMS limit significant declines in the relative weights for the MS–DRGs more broadly, including by establishing a cap on the degree to which the relative weight for an MS–DRG may decline from one fiscal year to the next. For prior fiscal years, as previously discussed, we have adopted limited, temporary measures to address potentially substantial declines in the relative weights in certain outlier circumstances to mitigate the impacts of such declines. However, we have also acknowledged commenters' concerns related to significant reductions in the weights for other MS–DRGs, in particular low volume MS–DRGs. For these low volume MS–DRGs, fluctuations in the volume or mix of cases and/or the presence of a few high cost or low cost cases can have a disproportionate impact on the calculated relative weight, thus resulting in greater year-to-year variation in the relative weights for these MS–DRGs. This variation may reduce the predictability and stability of an individual hospital's Medicare payments from year-to-year. We also recognize that significant declines in the relative weights may occur for higher-volume MS–DRGs, with such fluctuations likewise affecting the predictability and stability of hospital payments.

In light of these concerns, we have further considered requests made by commenters that we address year-to-year fluctuations in relative weights, particularly for low volume MS–DRGs, and to mitigate the financial impacts of significant fluctuations. In consideration of the concerns that commenters have raised about year-to-year fluctuations in relative weights and the financial impacts of significant fluctuations, we stated in the proposed rule that we believe it would be appropriate to limit such fluctuations by applying a cap on reductions in the relative weight for an MS–DRG for a given fiscal year. Therefore, consistent with our statutory authority under section 1886(d)(4)(B) and (C) of the Act to assign and update appropriate weighting factors, we proposed a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. This proposal is consistent with our general authority to assign and update appropriate weighting factors as part of our annual reclassification of the MS–DRGs and recalibration of the relative weights under sections 1886(d)(4)(B) and (C)(i) of the Act, as well as the requirements of section 1886(d)(4)(C)(iii) of the Act, which specifies that the annual DRG reclassification and recalibration of the relative weights be made in a manner that ensures that aggregate payments to hospitals are not affected. In addition, we have authority to implement this proposed cap and the associated budget neutrality adjustment under our special exceptions and adjustments authority at section 1886(d)(5)(I)(i) of the Act, which similarly gives the Secretary broad authority to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. As discussed, we believe this cap on declines in the relative weights would be appropriate in order to promote predictability and stability in hospital payments and to mitigate the financial impacts of significant fluctuations in the weights. That is, by smoothing year-to-year changes in the MS–DRG relative weights, we stated that this proposal would provide greater predictability to hospitals, allowing time to adjust to significant changes to relative weights. Moreover, consistent with the budget neutrality requirement for annual updates to the relative weights, including our implementation of similar caps on significant declines in the relative weight for prior fiscal years, we believe that application of this proposed 10-percent cap on relative weight reductions should not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. Accordingly, we proposed to apply a budget neutrality adjustment to the standardized amount for all hospitals to ensure that application of the proposed 10-percent cap does not result in an increase or decrease of estimated aggregate payments. For a further discussion of the budget neutrality

adjustment, we refer readers to the Addendum of the proposed rule and this final rule.

Under this proposal, in cases where the relative weight for a MS–DRG would decrease by more than 10 percent in a given fiscal year, we proposed to limit the reduction to 10 percent for that fiscal year. For example, if the relative weight for an MS–DRG in FY 2022 is 1.100 and the relative weight for FY 2023 would otherwise be 0.9350, which would represent a decrease of 15 percent from FY 2022, the reduction would be limited to 10 percent, such that the proposed relative weight for FY 2023 for MS–DRG XYZ would be 0.9900 (that is, 0.90 × FY 2022 weight of 1.100). The proposed relative weights for FY 2023 as set forth in Table 5 associated with the proposed rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* reflect the application of this proposed cap.

As previously summarized, in the past, we have adopted a temporary cap of 20 percent on the decline in an MS–DRG's relative weight to address certain outlier circumstances. However, as also previously discussed, we recognize that hospitals may benefit from the phase-in of smaller declines in the relative weight that may nonetheless contribute to less stability and predictability in hospital payment rates. Accordingly, for purposes of this proposed permanent cap, we considered that a higher cap, such as the 20-percent cap that we have applied previously (see, for example, 82 FR 38103), would limit declines in the relative weights for fewer MS–DRGs (5 MS–DRGs in our analysis of the March 2022 update of the FY 2021 MedPAR claims), while a lower cap, such as a 5-percent cap, would limit declines in the relative weights for more MS–DRGs (92 MS–DRGs in our analysis of the March 2022 update of the FY 2021 MedPAR claims), but with a larger associated budget neutrality adjustment to the standardized amount. On balance, we stated that we believe that a 10-percent cap would mitigate financial impacts resulting from significant fluctuations in the relative weights, particularly for low volume MS–DRGs, without the larger budget neutrality adjustment associated with a smaller cap. We noted that this proposed policy would limit declines in the relative weight for 27 MS–DRGs, based on the FY 2021 claims data used for the proposed rule; based on the March 2022 update of the FY 2021 claims data used for this final rule, we note that it would limit declines in the relative weights for 31 MS–DRGs.

We noted that this proposed 10-percent cap on reductions to an MS–DRG's relative weight would apply only to a given MS–DRG with its current MS–DRG number. In cases where CMS creates new MS–DRGs or modifies the MS–DRGs as part of its annual reclassifications resulting in renumbering of one or more MS–DRGs, we proposed that this limit on the reduction in the relative weight would not apply to any MS–DRGs affected by the renumbering (that is, the proposed 10-percent cap would not apply to the relative weight for any new or renumbered MS–DRGs for the fiscal year). We proposed to modify the regulations at § 412.60(b) to reflect this proposed permanent cap on relative weight reductions. We sought comments on our proposal to apply a 10-percent cap on decreases in an MS–DRG relative weight from one fiscal year to the next.

Comment: Many commenters supported our proposal to cap yearly reductions in an MS–DRG's relative weight to 10%. Commenters stated that significant year-over-year reductions can disrupt patient access to medically necessary treatment, that large swings are inconsistent with the principle of payment stability, and that a permanent 10 percent cap would provide more time for providers to adjust to significant changes in relative weights. A commenter stated that a cap on relative weight decreases could incentivize greater innovation, as hospitals may avoid MS–DRGs with significant declines, even if they offer more innovative, cost-saving treatment approaches. This commenter stated that mitigating large year-to-year payment changes would encourage providers to use the most clinically appropriate care. Commenters also stated that the cap is particularly helpful for low volume services, as they stated that shifts in these MS–DRGs are not reflective of true changes in the cost of care.

Some commenters requested that CMS apply the cap in a non-budget neutral manner. A commenter requested that CMS monitor for any unintended consequences of the cap, given that it is budget neutral.

Many commenters requested that CMS finalize a permanent lower cap, with some commenters expressing concern that with a 10% cap, there are still sizable reductions for high-cost MS–DRGs. Other commenters requested that CMS finalize a one-year cap of 5%, followed by a permanent cap of 10%. Several commenters recommended a permanent 5% cap, while others requested CMS set the floor as low as possible. Some commenters noted that a broad range of MS–DRGs have weight fluctuations in FY 2023 due to unique circumstances, such as the first use of hospital data impacted by the COVID–19 PHE for IPPS ratesetting. A commenter stated that the 10% cap benefits mostly medical MS–DRGs, while many surgical MS–DRGs would experience reductions greater than 5 percent but less than 10 percent. This commenter stated that capping reductions at 5% is consistent with the rationale to blend hospital claims with and without COVID–19, due to the uncertainty around the degree to which FY 2021 will reflect hospitals' costs and case mix in FY 2023. One commenter noted that their analysis of the MS–DRG relative weights showed that the average yearly variation in relative weights was 5%, so a permanent 5% cap is more in line with historical MS–DRG variation. A commenter stated that there is precedent of a 5% cap in other parts of the IPPS, such as the wage index.

One commenter requested that if CMS finalizes a 10% cap, that the agency continue to monitor whether a 10% cap is appropriate. A commenter requested that CMS update this policy clearly and transparently, and with additional stakeholder input, on an annual basis to maintain stability and predictability.

Some commenters acknowledged that setting a lower threshold for the cap would necessitate a larger budget neutrality adjustment, but that the redistributive impact would be minimal overall. These commenters stated that on balance it is still preferable to smooth the impact of steep payment declines for a larger number of services.

One commenter stated that it is premature for CMS to adopt a permanent cap, and recommended that CMS implement the 10% cap for FY 2023 only without a budget neutrality offset. This commenter stated that as COVID–19 becomes more endemic in the population, and less severe and costly in hospitals, Medicare utilization would be expected to return to its former level of annual stability, negating the need for a permanent cap on reductions to relative weights.

A commenter requested that any caps on the maximum annual change to the MS–DRG relative weights should not apply to just decreases but to increases as well.

A commenter stated that any new MS–DRG or modified version of an existing MS–DRG would benefit from the 10% cap in subsequent years following its introduction or modification. This commenter requested that CMS apply the 10% cap to all MS–DRGs once the MS–DRG has been established and gone through at least one year of the relative weight setting

process. This commenter also requested that CMS consider how this type of policy could support long term payment stability for relative weights and hospital payments.

One commenter suggested that similar caps on payment reductions would be beneficial under the OPPS and PFS for revised or bundled coding updates.

Response: We appreciate commenters' support for and feedback on our proposal. However, we disagree with the suggestion that the proposed cap be applied in a non-budget neutral manner. As we stated in the IPPS/LTCH PPS proposed rule, our proposal is consistent with the requirements of section 1886(d)(4)(C)(iii) of the Act, which specifies that the annual DRG reclassification and recalibration of the relative weights be made in a manner that ensures that aggregate payments to hospitals are not affected. Consistent with this budget neutrality requirement for annual updates to the relative weights, we believe that application of this proposed 10-percent cap on relative weight reductions should not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. This is also consistent with our implementation of similar caps on significant declines in the relative weight for prior fiscal years, as previously summarized.

We appreciate commenters' feedback on the size of the cap on year-to-year declines in an MS–DRG's relative weight, however we disagree that we should finalize a lower cap, whether for one year or on a permanent basis. As discussed in the proposed rule, after considering larger and smaller caps, we determined that on balance, a 10-percent cap would promote predictability and mitigate financial impacts resulting from significant fluctuations in the relative weights, particularly for low volume MS–DRGs, without the larger budget neutrality adjustment associated with a smaller cap. With respect to commenters who stated that we should finalize a five percent cap because there were greater fluctuations due to the first use of the PHE data for ratesetting and that many surgical MS–DRGs would experience declines of between 5 and 10 percent, we note that declines in relative weights between 5 and 10 percent are not uncommon. For example, we note that prior to the PHE, and relative to the 25 medical MS–DRGs and 36 surgical MS–DRGs for which the FY 2023 relative weight is declining between 5 and 10 percent as compared to FY 2022 (based on the March 2022 update of the FY 2021 claims data used for this final rule), for the FY 2020 IPPS/LTCH PPS final rule, 27 surgical MS–DRGs and 21 medical MS–DRGs declined between 5 and 10 percent, and for the FY 2019 IPPS/LTCH PPS final rule, 32 surgical MS–DRGs and 25 medical MS–DRGs declined between 5 and 10 percent. Therefore, we do not believe that the number of MS–DRGs for which the FY 2023 relative weight is declining between 5 and 10 percent is unusual or necessarily related to the first use of the PHE data. We therefore continue to believe that a 10-percent cap strikes the appropriate balance between considerations of promoting predictability and mitigating financial impacts resulting from significant fluctuations in the relative weights, without the larger budget neutrality adjustment associated with a smaller cap. We acknowledge commenters' observation that most MS–DRGs impacted by the cap for FY 2023 are medical MS–DRGs; we note that the particular MS–DRGs impacted in a given year would be expected to fluctuate based on changes in the underlying data or as result of reclassifications.

With respect to the commenters who requested that CMS implement a 10-percent cap for one year only or update the policy on an annual basis, we believe that in order to better promote predictability and stability in hospital payments, it is appropriate to finalize a permanent 10-percent cap on year-to-year declines in the relative weight, beginning with the FY 2023 relative weights. We expect to continue to monitor the effects of this cap, including the number of MS–DRGs subject to the cap for any given fiscal year, and to present in the Addendum to the annual proposed and final rules the budget neutrality adjustment for reclassification and recalibration of the MS–DRG relative weights with application of this cap. We also anticipate continuing to make available on the CMS website a supplemental file demonstrating the application of the permanent 10 percent cap for future years.

With regard to the comment requesting that caps on maximum changes to an MS–DRG's relative weight apply to increases as well, as discussed in the IPPS/LTCH PPS proposed rule, our goal in smoothing year-to-year changes in the relative weights is to mitigate financial impacts associated with significant declines in an MS–DRG's relative weight and allow hospitals more time to adjust to such changes by phasing-in these declines. In cases where the underlying data or MS–DRG reclassifications result in an increase to an MS–DRG's relative weight, we do not believe a such a phase-in is appropriate.

With regard to new or modified MS–DRGs, we are clarifying that after the first fiscal year that these new or modified MS–DRGs take effect, any changes to the relative weights for those MS–DRGs would also be subject to the 10-percent cap.

With regard to the commenter's suggestion about long-term payment stability, we note that the goal of this policy is to smooth year-to-year changes.

With regard to similar caps on payment under other payment systems, we note that this comment is outside the scope of the proposals included in the FY 2023 IPPS/LTCH PPS proposed rule, and we are therefore not addressing this comment in this final rule. We may consider this comment in connection with future rulemaking.

After consideration of comments received, we are finalizing the proposed permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year and the associated budget neutrality adjustment to the standardized amount, as previously described in this section, beginning in FY 2023. We are also finalizing our proposed modifications to the regulations at § 412.60(b) to reflect this permanent cap on relative weight reductions. The final relative weights for FY 2023 as set forth in Table 5 associated with this final rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* reflect the application of this finalized cap. For a further discussion of the budget neutrality adjustment for FY 2023, we refer readers to the Addendum of this final rule.

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2020 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the

normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the proposed relative weight.

As discussed earlier in this section, we are finalizing our proposal to (a) use 50 percent of the relative weights calculated using all cases in the FY 2021 MedPAR data and 50 percent of the relative weights calculated without COVID–19 cases in the FY 2021 MedPAR data to calculate the relative weights for FY 2023; and (b) apply a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, beginning in FY 2023.

In developing the relative weights consistent with these finalized policies, we first created a set of relative weights using all applicable cases in the March 2022 update of the FY 2021 MedPAR data, using the methodology as described earlier in this section (Step 1). These relative weights were then normalized by an adjustment factor of 1.948410 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

Next, we created a set of relative weights using the March 2022 update of the FY 2021 MedPAR data excluding cases with a principal or secondary diagnosis of COVID–19 (ICD–10–CM diagnosis code U07.1), and otherwise using the methodology as described earlier in this section (Step 2). These relative weights were then normalized by an adjustment factor of 1.916445.

We then averaged the results of Step 1 and Step 2 (Step 3), and normalized these relative weights by applying an adjustment factor of 1.000212 (Step 4). This normalization adjustment is intended to ensure that this averaging methodology for recalibration of the FY 2023 relative weights neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

Finally, we applied the 10 percent cap to the relative weights for those MS–DRGs for which the relative weight as calculated in Step 4 would otherwise have declined by more than 10 percent from the FY 2022 relative weight (Step 5). Specifically, for those MS–DRGs for which the relative weight as calculated in Step 4 declined by more than 10 percent from the FY 2022 relative weight, we set the FY 2023 relative weight equal to 90 percent of the FY 2022 relative weight. The relative weights for FY 2023 as set forth in Table 5 associated with this final rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* reflect the application of this cap. We are also making available a supplemental file setting forth the relative weights as calculated with all cases (Step 1), excluding cases with a principal or secondary diagnosis of COVID–19 (Step 2), following application of the normalization factor and prior to the application of this cap (Step 4), and with the application of this cap (Step 5) along with the other supplemental files for this final rule, on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

The 19 national average CCRs for FY 2023 are as follows:

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Group	CCR
Routine Days	0.422
Intensive Days	0.341
Drugs	0.184
Supplies & Equipment	0.311
Implantable Devices	0.281
Inhalation Therapy	0.15
Therapy Services	0.283
Anesthesia	0.072
Labor & Delivery	0.366
Operating Room	0.165
Cardiology	0.094
Cardiac Catheterization	0.104
Laboratory	0.107
Radiology	0.137
MRIs	0.071
CT Scans	0.034
Emergency Room	0.155
Blood and Blood Products	0.255
Other Services	0.359

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We are proposed to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2023. Using data from the FY 2021 MedPAR file, there were 7 MS–DRGs that contain fewer than 10 cases. For FY 2023, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we proposed to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2022 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2022 to FY 2023. The crosswalk table is as follows.

Low-Volume MS-DRG	MS-DRG Title	Crosswalk to MS-DRG
789	Neonates, Died or Transferred to Another Acute Care Facility	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	Final FY 2022 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

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We did not receive any public comments on our proposals and we are finalizing our proposals without modification.

F. Add-On Payments for New Services and Technologies for FY 2023

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. The regulations at 42 CFR 412.87 implement these provisions and § 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d). We note that section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act. Therefore, as discussed in prior rulemaking (72 FR 47307 through 47308), we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs.

In this rule, we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For further discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

a. New Technology Add-On Payment Criteria

(1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will no longer be considered ''new'' for purposes of new medical service or technology add-on payments after CMS has recalibrated the MS–DRGs, based on available data, to reflect the cost of the technology. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically whether: (1) a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) a product is assigned to the same or a different MS–DRG; and (3) the new use

of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

(2) Cost Criterion

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75% of the standardized amount (increased to reflect the difference between cost and charges) or 75% of one standard deviation beyond the geometric mean standardized charge for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs if the new medical service or technology occurs in many different MS–DRGs). The MS–DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2023 are presented in a data file that is available, along with the other data files associated with the FY 2022 IPPS/LTCH PPS final rule and correction notice, on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

We note that, under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58603 through 58605), beginning with FY 2022, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the proposed thresholds for applications for new technology add-on payments for FY 2024 were presented in a data file that is available on the CMS website, along with the other data files associated with the FY 2023 final rule, by clicking on the FY 2023 IPPS final rule home page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, in the FY 2022 IPPS/LTCH PPS final rule, we finalized our proposal to use the FY 2019 MedPAR claims data where we ordinarily would have used the FY 2020 MedPAR claims data for purposes of FY 2022 ratesetting. Consistent with that final policy, we finalized our proposal to use the FY 2019 claims data to set the thresholds for applications for new technology add-on payments for FY 2023. We note that, for the reasons discussed in section I.F. of the preamble of the proposed rule and this final rule, we proposed to use the FY 2021 MedPAR claims data for FY 2023 ratesetting, with certain proposed modifications to our relative weight setting and outlier methodologies. Consistent with this proposal, for the FY 2024 proposed threshold values, we proposed to use the FY 2021 claims data to set the proposed thresholds for applications for new technology add-on payments for FY 2024. In addition, as discussed in section III.E.1.c. of the proposed rule and this final rule, we proposed to use an averaging approach for calculating the FY 2023 relative weights, to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries as compared to FY 2021. Specifically, we proposed to average the relative weights as calculated with and without COVID–19 cases in the FY 2021 data to determine the MS–DRG relative weights for FY 2023. Certain steps of calculating the thresholds for applications for new technology add-on payments use the same charge data that is used to calculate the MS–DRG weights. As a result, different average charges per MS–DRG are calculated using the charge data for the relative weights as calculated with and without COVID–19 cases. Therefore, for purposes of calculating the FY 2024 thresholds, we also proposed to average the data in the steps of the calculation that use charge data from the calculation of the MS–DRG weights. In addition, as discussed in section I.O. of the appendix of the FY 2023 IPPS/LTCH proposed rule (87 FR 28740 through 28741), we also considered, as an alternative to our proposal, calculating the FY 2023 MS–DRG relative weights without the proposed averaging approach to account for COVID–19 cases. In connection with this alternative approach, we made available the threshold values as calculated without this averaged data on the ''FY 2023 Final Rule Homepage'' at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*, as well as other supplemental files as discussed further in section I.O. of Appendix A of this final rule.

As discussed in section I.F. of the preamble of this final rule, we are finalizing our proposal to use the FY 2021 MedPAR claims data for FY 2023 ratesetting. Also, as discussed in section II.E of this final rule we are finalizing our proposal to average the relative weights as calculated with and without COVID–19 cases in the FY 2021 data to determine the MS–DRG relative weights for FY 2023. We did not receive any public comments on our proposal to average the data in the steps of the calculation of the FY 2024 thresholds that use charge data from the calculation of the MS–DRG weights, as discussed in the proposed rule. Accordingly, in this final rule, we are finalizing to use FY 2021 claims data to set the thresholds for applications for new technology add-on payments for FY 2024, and we are also finalizing to average the data in the steps of the calculation of the FY 2024 thresholds that use charge data from the calculation of the MS–DRG weights, as described previously. The finalized thresholds for applications for new technology add-on payments for FY 2024 are presented in a data file that is available on the CMS website, along with the other data files associated with this FY 2023 final rule, by clicking on the FY 2023 IPPS Final Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

In the September 7, 2001, final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial

validation and analysis of the data. We also discussed in the September 7, 2001, final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for further information on this issue.

(3) Substantial Clinical Improvement Criterion

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292), we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

- Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.
- The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.
- The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS final rule (67 FR 50015), that while FDA has regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not rely upon FDA criteria in our evaluation of substantial clinical improvement for purposes of determining what drugs, devices, or technologies qualify for new technology add-on payments under Medicare. This criterion does not depend on the standard of safety and effectiveness on which FDA relies but on a demonstration of substantial clinical improvement in the Medicare population.

b. Alternative Inpatient New Technology Add-On Payment Pathway

Beginning with applications for FY 2021 new technology add-on payments, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program may qualify for the new technology add-on payment under an alternative pathway. Additionally, under the regulations at § 412.87(d) for certain antimicrobial products, beginning with FY 2021, a drug that is designated by FDA as a Qualified Infectious Disease Product (QIDP), and, beginning with FY 2022, a drug that is approved by FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), may also qualify for the new technology add-on payment under an alternative pathway. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy. We note that a technology is not required to have the specified FDA designation at the time the new technology add-on payment application is submitted. CMS reviews the application based on the information provided by the applicant only under the alternative pathway specified by the applicant at the time of new technology add-on payment application submission. However, to receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable.

(1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of FDA's Breakthrough Devices Program and received FDA marketing authorization, it will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves,

relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) and that is part of FDA's Breakthrough Devices Program will need to meet the requirements of § 412.87(c). We note that in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736), we clarified our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736) for further discussion regarding this clarification.

(2) Alternative Pathway for Certain Antimicrobial Products

For applications received for new technology add-on payments for certain antimicrobial products, beginning with FY 2021, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, and, beginning with FY 2022, if a drug is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway, it will be considered not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway for QIDPs and LPADs, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP or approved under the LPAD pathway will need to meet the requirements of § 412.87(d).

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy. We note, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739), we clarified that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation. We also finalized our policy to expand our alternative new technology add-on payment pathway for certain antimicrobial products to include products approved under the LPAD pathway and used for the indication approved under the LPAD pathway.

c. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. As noted previously, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (72 FR 47307 through 47308).

For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying operating cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), CMS made an add-on payment equal to the lesser of: (1) 50% of the costs of the new medical service or technology; or (2) 50% of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65% of the costs of the new medical service or technology; or (2) 65% of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75% of the costs of the new medical service or technology; or (2) 75% of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product approved under FDA's LPAD pathway, beginning with discharges on or after October 1, 2020, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75% of the costs of the new medical service or technology; or (2) 75% of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65% (or 75% for certain antimicrobial products (QIDPs and LPADs)) of the estimated costs of the new technology or medical service. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300) for further discussion on the increase in the new technology add-on payment beginning with discharges on or after October 1, 2019.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

d. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulation at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We specified that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the

year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to the regulation to indicate that new technologies must receive FDA marketing authorization (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request, or approval of a New Drug Application (NDA)) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Consistent with our longstanding policy, we consider FDA marketing authorization as representing that a product has received FDA approval or clearance when considering eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

Additionally, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58739 through 58742), we finalized our proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

e. New Technology Liaisons

Many interested parties (including device/biologic/drug developers or manufacturers, industry consultants, others) engage CMS for coverage, coding, and payment questions or concerns. In order to streamline engagement by centralizing the different innovation pathways within CMS including new technology add-on payments, CMS has established a team of new technology liaisons that can serve as an initial resource for interested parties. This team is available to assist with all of the following:

- Help to point interested parties to or provide information and resources where possible regarding process, requirements, and timelines.
- Coordinate and facilitate opportunities for interested parties to engage with various CMS components.
- Serve as a primary point of contact for interested parties and provide updates on developments where possible or appropriate.

We received many questions from interested parties with respect to pursuing new technology add-on payments who may not be entirely familiar with working with CMS. While we encourage interested parties to first review our resources available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech*, we know that there may be additional questions about the application process. Interested parties with further questions about Medicare's coverage, coding, and payment processes, and about how they can navigate these processes, whether for new technology add-on payments or otherwise, can contact the new technology liaison team at *MedicareInnovation@cms.hhs.gov*.

f. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2024 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways as previously described), along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. CMS will review the application based on the information provided by the applicant under the pathway specified by the applicant at the time of application submission. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*. To allow interested parties to identify the new medical services or technologies under review before the publication of the final rule for FY 2024, the CMS website also will post the tracking forms completed by each applicant. We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the Paper Reduction Act (PRA) and approved under OMB control number 0938–1347, and has an expiration date of 11/30/2023.

As discussed previously, in the FY 2020 IPPS/LTCH PPS final rule, we adopted an alternative inpatient new technology add-on payment pathway for certain transformative new devices and for Qualified Infectious Disease Products, as set forth in the regulations at § 412.87(c) and (d). The change in burden associated with these changes to the new technology add-on payment application process were discussed in a revision of the information collection requirement (ICR) request currently approved under OMB control number 0938–1347, with an expiration date of November 30, 2023. In accordance with the implementing regulations of the PRA, we detailed the revisions of the ICR and published the required 60-day notice on August 15, 2019 (84 FR 41723), and 30-day notice on December 17, 2019 (84 FR 68936), to solicit public comments.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement. The process for evaluating new medical service and technology applications requires the Secretary to do all of the following:

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries.
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending.
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement.
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data

regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2023 prior to publication of the FY 2023 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on September 24, 2021 (86 FR 53056), and held a virtual town hall meeting on December 14, 2021. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2023 new medical service and technology add-on payment applications before the publication of the FY 2023 IPPS/LTCH IPPS proposed rule.

Approximately 378 individuals registered to attend the virtual town hall meeting. We posted the recordings of the virtual town hall on the CMS web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech*.

We considered each applicant's presentation made at the town hall meeting, as well as written comments received by the December 27, 2021, deadline, in our evaluation of the new technology add-on payment applications for FY 2023 in the development of the FY 2023 IPPS/LTCH PPS proposed rule. In response to the published notice and the December 14, 2021, New Technology Town Hall meeting, we received written comments regarding the applications for FY 2023 new technology add on payments. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (86 FR 53056 through 53059), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion with regard to pending new technology add-on payment applications for FY 2023. Therefore, we did not summarize the written comments in the proposed rule that are unrelated to the substantial clinical improvement criterion. In section II.F.6. of the preamble of the proposed rule, we summarized comments regarding individual applications, or, if applicable, indicated that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at *https://www.cms.gov/medicare/icd-10/2021-icd-10-pcs*, including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

As discussed in more detail in section II.F.8. of the preamble of this final rule, in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to use NDCs instead of ICD–10–PCS Section ''X'' codes to identify cases involving the use of therapeutic agents approved for new technology add-on payments beginning with a transitional period in FY 2023. We refer the reader to section II.F.8. of the preamble of this final rule for a full discussion of this proposal and the comments received.

4. New COVID–19 Treatments Add-On Payment (NCTAP)

In response to the COVID–19 public health emergency (PHE), we established the New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71157 through 71158). We believe that as drugs and biological products become available and are authorized for emergency use or approved by FDA for the treatment of COVID–19 in the inpatient setting, it is appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID–19 treatments during the PHE. Therefore, effective for discharges occurring on or after November 2, 2020 and until the end of the PHE for COVID–19, we established the NCTAP to pay hospitals the lesser of (1) 65% of the operating outlier threshold for the claim or (2) 65% of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID–19.

In the FY 2022 IPPS/LTCH PPS final rule, we finalized a change to our policy to extend NCTAP through the end of the FY in which the PHE ends for all eligible products in order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE. We also finalized that, for a drug or biological product eligible for NCTAP that is also approved for new technology add-on payments, we will reduce the NCTAP for an eligible case by the amount of any new technology add-on payments so that we do not create a financial disincentive between technologies eligible for both the new technology add-on payment and NCTAP compared to technologies eligible for NCTAP only (85 FR 45162).

Further information about NCTAP, including updates and a list of currently eligible drugs and biologicals, is available on the CMS website at *https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap*.

5. FY 2023 Status of Technologies Receiving New Technology Add-On Payments for FY 2022

In this section of the final rule, we discuss the proposed FY 2023 status of 37 technologies approved for FY 2022 new technology add-on payments, including 2 technologies approved for 2 separate add-on payments for different indications (RECARBRIO™ and FETROJA®), and our finalized policies, as set forth in the tables that follow. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. We note that, as discussed later in this section, we provided a 1-year extension of new technology add-on payments for FY 2022 for 13 technologies for which the new technology add-on payment would otherwise have been discontinued beginning in FY 2022 using our authority under section 1886(d)(5)(I) of the Act.

Additionally, we note that we conditionally approved CONTEPO for FY 2022 new technology add-on payments under the alternative pathway for certain antimicrobial products (86 FR 45155), subject to the technology receiving FDA marketing authorization by July 1, 2022. In the FY 2023 IPPS LTCH/PPS proposed rule, we stated that if CONTEPO receives FDA marketing authorization prior to July 1, 2022, we were proposing to continue making new technology add-on payments for CONTEPO for FY 2023. We stated that if CONTEPO does not receive FDA marketing authorization by July 1, 2022, then it would not be eligible for new technology add-on payments for FY 2022, and therefore would not be eligible for the continuation of new technology add-on payments for FY 2023. Because CONTEPO did not receive FDA approval by July 1, 2022, no new technology add-on payments will be made for cases involving the use of CONTEPO for FY 2022, and CONTEPO is therefore not eligible for the continuation of new technology add-on payments for FY 2023.

a. FY 2023 Status of Technologies Approved for FY 2022 New Technology Add-On Payments

As noted previously, we used our authority under section 1886(d)(5)(I) of the Act to allow a 1-year extension of new technology add-on payments for FY 2022 for 13 technologies for which the add-on payments would otherwise be discontinued beginning in FY 2022 because the technologies would no longer be considered ''new'' for FY 2022. In this section, we discuss the proposed FY 2023 status for the remaining 24 technologies approved for FY 2022 new technology add-on payments and our finalized policies. Specifically, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28210–28212), we presented our proposals to continue the new technology add-on payment for FY 2023 for those technologies that were approved for the new technology add-on payment for FY 2022 and which would still be considered ''new'' for purposes of new technology add-on payments for FY 2023. We also presented our proposals to discontinue new technology add-on payment for FY 2023 for those technologies that were approved for the new technology add-on payment for FY 2022 and which would no longer be considered ''new'' for purposes of new technology add-on payments for FY 2023.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

In the proposed rule, we provided a table listing the technologies for which we proposed to continue making new technology add-on payments for FY 2023 because they would still be considered ''new'' for purposes of new technology add-on payments (87 FR 28213 through 28214). This table also presented the newness start date, new technology add-on payment start date, 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments for each technology. We referred readers to the final rules cited in the table for a complete discussion of the new technology add-on payment application, coding and payment amount for each of these technologies, including the applicable indications and discussion of the newness start date.

We invited public comments on our proposals to continue new technology add-on payments for FY 2023 for the technologies listed in the table in the proposed rule.

Comment: Commenters overwhelmingly supported our proposed continuation of new technology add-on payments for FY 2023 for those technologies that were approved for the new technology add-on payment for FY 2022 and which would still be considered ''new'' for purposes of new technology add-on payments for FY 2023.

Response: We appreciate the commenters' support.

In the proposed rule, we noted, as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45104 through 45107), on May 1, 2020, VEKLURY® (remdesivir) received an Emergency Use Authorization (EUA) from FDA for the treatment of suspected or laboratory confirmed COVID–19 in adults and children hospitalized with severe disease. The applicant asserted that between July 1, 2020 and September 30, 2020, it entered into an agreement with the U.S. Government to allocate and distribute commercially-available VEKLURY® across the country. The applicant stated that under this agreement, the first sale of VEKLURY® was completed on July 10, 2020. The applicant stated that they transitioned to a more traditional, unallocated model of distribution as of October 1, 2020. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45107), we determined that VEKLURY® meets the newness criterion with an indication for use in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID–19 requiring hospitalization. We stated that consistent with our longstanding policy, we considered the newness period for VEKLURY® to begin on October 22, 2020, when the NDA for VEKLURY® was approved by FDA for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID–19 requiring hospitalization. We also discussed comments solicited regarding the newness period for products available through an EUA for COVID–19 in section II.F.7. of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159 through 45160), including comments we received regarding the potential variability in cost estimates for technologies available under an EUA due to government price subsidies or variable treatment practices in the context of the global pandemic and comments suggesting that CMS monitor pricing changes for products available under an EUA once a product receives full marketing authorization, instead of basing the newness period on data that may have become available under an EUA, and indicated that we would consider these comments for future rulemaking.

We stated in the proposed rule (87 FR 28212) that after further review of the information provided by the applicant, we believed that additional information related to VEKLURY®'s commercial availability is relevant to assessing the start of the newness period for VEKLURY®. We noted that the applicant stated that once VEKLURY® was issued an EUA, from May through June 2020, the entire existing supply of VEKLURY® was donated worldwide and distributed to hospitals free of charge.[29] The applicant further stated that the commercial list price of the technology was announced when it entered into the agreement with the U.S.

[29] *https://stories.gilead.com/articles/an-update-on-covid-19-from-our-chairman-and-ceo.*

Government previously described, in anticipation of the post-donation phase. Under this agreement, the U.S. Government allocated VEKLURY® to each hospital, and the hospitals would then choose to purchase quantities of VEKLURY® directly from the applicant's subsidiary who was the sole distributor.[30] [31]

We stated in the proposed rule that we continue to believe this issue is complex, particularly as it relates to VEKLURY® as a technology that has been available under both an EUA and an NDA. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159 through 45160), while an EUA is not marketing authorization within the meaning of § 412.87(e)(2) for purposes of eligibility for new technology add-on payments, data reflecting the costs of products that have received an EUA could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance. In the case of VEKLURY®, we stated that we believe that there may be unique considerations in determining the start of the newness period in light of the donation period, during which the technology was distributed at no cost. Accordingly, while we noted that we continue to believe that data reflecting the costs of a product that has received an EUA could become available as soon as the date of EUA issuance for that product, we believed that with respect to VEKLURY®, such data may not have become available until after the end of the donation period, when the technology became commercially available, on July 1, 2020. For these reasons, after further consideration, we stated that we believe the newness period for VEKLURY® may more appropriately begin on July 1, 2020, the date on which the technology became available for sale under the allocation agreement. We noted that VEKLURY® would still be considered new for FY 2023 regardless of whether the newness period began on May 1 (the date of the EUA), July 1 (the date the donation phase ended), October 22 (the date of the NDA), or some other date in between, as in all cases the three-year anniversary date would occur after April 1, 2023, and therefore the product would remain eligible for FY 2023 new technology add-on payments.

Therefore, we proposed to continue new technology add-on payments for VEKLURY® for FY 2023. We invited public comments on this proposal, including the newness start date for VEKLURY®. As discussed, while we continue to believe that data reflecting the costs of a product that has received an EUA could become available as soon as the date of EUA issuance for that product, we also recognize that there may be unique considerations in determining the start of the newness period for a product available under an EUA. We are continuing to consider the comments as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159) regarding the newness period for products available through an EUA for COVID–19, and we welcomed additional comments in the proposed rule.

Comment: The applicant submitted a comment with respect to the start of the newness period for VEKLURY®. The applicant noted that there is no material impact on eligibility for new technology add-on payments for VEKLURY®, regardless of whether CMS uses July 1 2020, the date VEKLURY® became available for sale under the allocation agreement, or October 22, 2020, the date of FDA approval as the start of the newness period for VEKLURY®. The applicant maintained that using either date and applying CMS' standard methodology of calculating the period of eligibility for new technology add-on payments would result in VEKLURY® staying within its newness period through FY 2023 (October 1, 2022–September 30, 2023), and that VEKLURY® would not be eligible for new technology add-on payments in FY 2024 in either circumstance.

The applicant stated that the primary effect of CMS' revisiting of the VEKLURY® newness determination would be to set a precedent that would affect the future eligibility for new technology add-on payments of other EUA products. To this point, the applicant referred to the FY 2022 IPPS final rule where CMS originally finalized the newness date for VEKLURY® and stated that products that do not have FDA approval or clearance, including products available in the U.S. under an EUA, are not eligible for new technology add-on payments (86 FR 45106–07). The applicant also pointed to 42 CFR 412.87(b) which outlines additional eligibility criteria for substantial clinical improvement, cost, and newness that must all be met in order for a product to be eligible for new technology add-on payments. The applicant stated it is reasonable to assume these requirements should not be in conflict with respect to how they are evaluated and implemented, including with respect to the timelines applied to the determination of eligibility for new technology add-on payments.

Furthermore, the applicant stated that CMS confirmed that using the date of FDA approval as the beginning of the newness period for VEKLURY® was consistent with its longstanding policy, with the commenter referencing CMS's statement that generally, its policy is ''to begin the newness period on the date of FDA approval or clearance or, *if later,* the date of availability of the product on the U.S. market, when [data] reflecting the costs of the technology begin to become available for the recalibration of the MS–DRGs'' (86 FR 45159) (emphasis added). The applicant asserted that using a date prior to FDA approval as the beginning of the newness period would therefore serve as a departure from how CMS has traditionally determined newness for the purposes of new technology add-on payments, as there is no precedent to use a date earlier than FDA approval as the date of market availability.

The applicant stated that VEKLURY®'s distribution and commercialization framework over the course of the COVID–19 pandemic, through which VEKLURY® was available through emergency and compassionate use programs, donations, and a post-donation model in collaboration with the federal government, were all implemented prior to VEKLURY® receiving FDA approval and does not in any way resemble the current distribution and reimbursement paradigm. The applicant further stated that its experience during the EUA period does not reflect the type of distribution and reimbursement environment that would support a newness period that begins prior to the FDA approval date for VEKLURY®. The applicant stated that the data collected on utilization and resource use during the EUA period likely would not be representative of utilization or resource use following FDA approval, given that the EUA period occurred within the context of a global pandemic and a time of extreme uncertainty for the health care system. The applicant pointed to CMS's use of FY 2019 data for FY 2022 ratesetting for circumstances where the FY 2020 data was significantly impacted by the COVID–19 PHE, and reasoned that VEKLURY®'s utilization would be similarly impacted by the PHE as its EUA period occurred almost entirely in FY 2020.

[30] Remdesivir for the Commercial Marketplace. *https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/factsheet.aspx.*

[31] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (ASPR). ASPR's Portfolio of COVID–19 Medical Countermeasures Made Available as a Licensed Product. *https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/Veklury.aspx.*

The applicant urged that CMS continue to determine the start of the newness period for VEKLURY® and other products originally available in the U.S. under an EUA using what it stated was the same policy CMS has applied for all other products approved for new technology add-on payment, which is to use the date of FDA approval or, if later, the date of market availability in the U.S. For VEKLURY®, the applicant stated that this date is October 22, 2020, the date of FDA approval. The applicant stated that maintaining this policy aligns to existing precedent, simplifies the newness determination process, and applies a consistent policy across products.

Response: We thank the applicant for its input. As discussed in the FY 2018 IPPS final rule (82 FR 38115), the period of newness does not necessarily start with the approval date for the medical service or technology and instead begins with availability of the product on the U.S. market, which is when data become available. We have consistently applied this standard and believe that it is consistent with the purpose of new technology add-on payments. Therefore, while generally our policy is to begin the newness period on the date of FDA approval or clearance, we may also consider a documented delay in the technology's market availability in our determination of newness (77 FR 53348 and 70 FR 47341). Accordingly, we agree that in general, we have begun the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product onto the US market, based on such a documented delay, as that is when data reflecting the costs of the technology begin to become available. However, as we discussed in the FY 2022 final rule, for a product with an EUA, the data reflecting the costs of that product could become available as soon as the date of EUA issuance, and prior to FDA approval or clearance. Therefore, while a product approved under an EUA and for which there is data reflecting the costs of the technology prior to FDA approval may be factually distinct from a product for which there is a documented delay in marketing availability following FDA approval, we disagree that beginning the newness period on the date of EUA issuance and prior to FDA approval would be inconsistent with our longstanding policy of beginning the newness period with the availability of the product on the U.S. market. With regard to the additional criteria for eligibility for the new technology add-on payment, we refer readers to the FY 2022 final rule for our discussion of the eligibility of a product available only through an EUA for the new technology add-on payment under section 412.87(e)(2) (86 FR 45048 through 45049), as well as the comment solicitation on the new technology add-on payment newness period for products available through an EUA (86 FR 45159 through 45160). With respect to the applicant's comment that VEKLURY®'s utilization may have been impacted by the COVID–19 PHE during the EUA period, we note that the EUA for VEKLURY® was directly related to COVID–19.

We agree with the applicant that regardless of whether VEKLURY's® newness period begins on July 1, 2020, the date VEKLURY® became available for sale under the allocation agreement, or October 22, 2020, the date of FDA approval, the application of CMS' standard methodology for determining the period of eligibility for new technology add-on payments results in VEKLURY® remaining within its newness period through FY 2023 (October 1, 2022–September 30, 2023), and that VEKLURY® would not be eligible for new technology add-on payments in FY 2024 in either circumstance. Accordingly, we are finalizing our proposal to continue new technology add-on payments for VEKLURY® for FY 2023, as reflected in Table II.F.-01 of this final rule. As stated previously, we also recognize that there may be unique considerations associated with determining the start of the newness period for a product available under an EUA prior to receiving FDA approval, including as discussed in the applicant's comments. Accordingly, we will continue to consider the comments received regarding the newness period for products available through an EUA for COVID–19 for future rulemaking.

In the FY 2023 IPPS/LTCH PPS proposed rule, we noted that we also proposed to continue new technology add-on payments for Caption Guidance for FY 2023, a technology sold on a subscription basis. We stated we continued to welcome comments from the public as to the appropriate method to determine a cost per case for technologies sold on a subscription basis, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment.

We did not receive any comments regarding the appropriate method to determine a cost per case for technologies sold on a subscription basis, and we will continue to consider these issues.

Comment: The applicant for Abecma® submitted a comment stating its strong support for the continuation of new technology add-on payments for Abecma® for FY 2023. The applicant stated that although Abecma® received FDA approval on March 26, 2021, it did not enter the U.S. market until May 10, 2021, when the date of first sale occurred and the new technology was first reflected in claims data. The applicant stated that the newness period for Abecma® should therefore begin on May 10, 2021 as CMS' policy is to begin the newness period on the date of a product's entry onto the U.S. market. The applicant further stated that Abecma®'s new technology add-on payment status should be extended beyond FY 2023, as CMS policy is to extend new technology add-on payments for an additional year when the 3-year anniversary of market entry occurs in the latter half of the fiscal year.

Response: We thank the applicant for its comment. As stated previously, while CMS may consider a documented delay in the technology's market availability in our determination of newness, our policy for determining whether to extend new technology add-on payments for an additional year generally applies regardless of the volume of claims for the technology after the beginning of the newness period (83 FR 41280). We do not consider the date of first sale of a product as an indicator of the entry of a product onto the U.S. market. The applicant states that the date of first sale of Abecma® was May 10, 2021, but it is unclear from the information provided when the technology first became *available* for sale and, absent additional information from the applicant, we cannot determine a newness date based on a documented delay in the technology's availability on the U.S. market.

We further note that, as discussed in section II.F.6.a. of the preamble of this final rule, because CARVYKTI™ is substantially similar to ABECMA®, we are using a single cost for purposes of determining the new technology add-on payment amount for CARVYKTI™ and ABECMA® for FY 2023. As discussed in section II.F.6.a., we determined a weighted average of the cost of CARVYKTI™ and ABECMA® based upon the projected numbers of cases involving each technology to determine

the maximum new technology add-on payment. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 420 cases (241 plus 179). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case weighted percentages: 57% for CARVYKTI™ and 43% for ABECMA®. We then multiplied the cost per case for the manufacturer specific drug by the case-weighted percentage (0.57 * $465,000 = $265,050 for CARVYKTI™ and 0.43 * $419,500 = $180,385 for ABECMA®). This resulted in a case-weighted average cost of $445,435 for the technology.

Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of CARVYKTI™ and ABECMA® is $289,532.75 for FY 2023, as is reflected in Table II.F.-01 of this final rule.

Comment: Several commenters requested that CMS update the maximum new technology add-on payment amount to reflect the current Wholesale Acquisition Cost (WAC) per vial of their respective technologies. The applicant for Zepzelca™ requested the maximum new technology add-on payment amount for Zepzelca™ be updated from $8,622.90 to $9,145.50 to reflect the updated WAC of $7,035 per vial of Zepzelca™. The applicant for Cosela™ requested the maximum new technology add-on payment amount for Cosela™ be updated to reflect the updated WAC of $1,439 per vial of Cosela™.

Response: We appreciate the updated cost information. Zepzelca™'s current new technology add-on payment amount is $8,622.90 for 2 single-dose vials and reflects the WAC at the time of Zepzelca™'s entry onto the U.S. market (2 single-dose vials per dose × $6,633 per vial multiplied by 0.65). For FY 2023, the maximum new technology add-on payment amount using the updated WAC is $9,145.50 (2 single-dose vials per dose × $7,035 per vial multiplied by 0.65), as reflected in Table II.F.-01 in this final rule.

Similarly, Cosela™'s current new technology add-on payment amount is $5,526.30 (3 doses of Cosela™ × 2 single-dose vials per dose × $1,417 per vial multiplied by 0.65). For FY 2023, the maximum new technology add-on payment amount using the updated WAC is $5,612.10 (3 doses of Cosela™ × 2 single-dose vials × $1,439 per vial multiplied by 0.65) as reflected in Table II.F.-01 in this final rule.

After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for FY 2023 for the technologies that were approved for new technology add-on payment for FY 2022 and would still be considered ''new'' for purposes of new technology add-on payments for FY 2023, as listed in the proposed rule and in the following Table II.F.-01 in this section of this final rule.

We note that Table II.F.-01 below is the same as Table II.F.-02 that was presented in the proposed rule, but Table II.F.-01 in this final rule includes the updated cost information for Zepzelca™, Cosela™, and Abecma®, as discussed previously. Table II.F.-01 also includes updated cost information for aScope Duodeno® to reflect the cost of the technology alone, rather than a case-weighted average with EXALT Model D™, as discussed later in this section. The following table also presents the newness start date, new technology add-on payment start date, 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, maximum add-on payment amount, and coding assignments. We refer readers to the final rules cited in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

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TABLE II.F.-01: CONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2022 NEW TECHNOLOGY ADD-ON PAYMENTS STILL CONSIDERED NEW FOR FY 2023 BECAUSE 3-YEAR ANNIVERSARY DATE WILL OCCUR ON OR AFTER APRIL 1, 2023

	Technology	FDA/Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto US Market	Previous Final Rule Citations	Maximum NTAP Amount for FY 2023	Coding Used to Identify Cases Eligible for NTAP
1	*Rybrevant™*	*05/21/2021*	*10/1/2021*	*5/21/2024*	86 FR 44988 through 44996	$6,405.89	XW033B7 or XW043B7
2	*Cosela™*	*02/12/2021*	*10/1/2021*	*2/12/2024*	86 FR 45008 through 45017	$5,612.10	XW03377 or XW04377
3	*ABECMA®*	*03/26/2021*	*10/1/2021*	*3/26/2024*	86 FR 45028 through 45035	$289,532.75	XW033K7 or XW043K7
4	*StrataGraft®*	*06/15/2021*	*10/1/2021*	*6/15/2024*	86 FR 45079 through 45090	$44,200.00	XHRPXF7
5	*TECARTUS®*	*07/24/2020*	*10/1/2021*	*7/4/2023*	86 FR 45090 through 45104	$259,350.00	XW033M7 or XW043M7
6	*VEKLURY®*	*07/1/2020**	*10/1/2021*	*7/1/2023**	86 FR 45104 through 45116	$2,028.00	XW033E5 or XW043E5
7	*Zepzelca™*	*06/15/2020*	*10/1/2021*	*6/15/2023*	86 FR 45116 through 45126	$9,145.50	XW03387 or XW04387
8	*aprevo® Intervertebral Body Fusion Device*	*12/03/2020 (ALIF and LLIF) 6/30/2021 (TLIF)*	*10/1/2021*	*12/03/2023 (ALIF and LLIF) 6/30/2024 (TLIF)*	86 FR 45127 through 45133 86 FR 67875	$40,950.00	XRGA0R7 or XRGA3R7 or XRGA4R7 or XRGB0R7 or XRGB3R7 or XRGB4R7 or XRGC0R7 or XRGC3R7 or XRGC4R7 or XRGD0R7 or XRGD3R7 or XRGD4R7
9	*aScope® Duodeno*	*07/17/2020*	*10/1/2021*	*7/17/2023*	86 FR 45133 through 45135	$1,296.75	XFJB8A7 or XFJD8A7
10	*Caption Guidance™*	*09/15/2020*	*10/1/2021*	*9/15/2023*	86 FR 45135 through 45138	$1,868.10	X2JAX47
11	*Harmony™ Transcatheter Pulmonary Valve (TPV) System*	*03/26/2021*	*10/1/2021*	*3/26/2024*	86 FR 45146 through 45149	$26,975.00	02RH38M
12	*Intercept® (PRCFC)*	*05/05/2021*	*10/1/2021*	*5/05/2024*	86 FR 45149 through 45150 86 FR 67875	$2,535.00	30233D1 or 30243D1 in combination with one of the following D62, D65, D68.2, D68.4 or D68.9
13	*ShockWave C2 Intravascular Lithotripsy (IVL) System*	*02/12/2021*	*10/1/2021*	*2/12/2024*	86 FR 45151 through 45153	$3,666.00	02F03ZZ or 02F13ZZ or 02F23ZZ or 02F33ZZ
14	*Fetroja® (HABP/VABP)*	*09/25/2020*	*10/1/2021*	*9/25/2023*	86 FR 45156 through 45157 86 FR 67876	$8,579.84	XW033A6 or XW043A6 in combination with ICD-10-CM code Y95 and one of the following: J14, J15.0, J15.1, J15.5, J15.6, J15.8, OR XW033A6 or XW043A6 in combination with J95.851

							and one of the following: B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89
15	*Recarbrio™ (HABP/VABP)*	*06/04/2020*	*10/1/2021*	*6/04/2023*	86 FR 45157 through 45158 86 FR 58023 through 58024 86 FR 67876	$9,576.51	XW033U5 or XW043U5 in combination with ICD-10-CM code Y95 and one of the following: J14, J15.0, J15.1, J15.5, J15.6, J15.8, OR XW033U5 or XW043U5 in combination with J95.851 and one of the following: B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89

*See the previous discussion regarding the start of the newness period for VEKLURY®.

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In the proposed rule, we provided a table listing the technologies for which we proposed to discontinue making new technology add-on payments for FY 2023 because they are no longer ''new'' for purposes of new technology add-on payments (87 FR 28211). This table also presented the newness start date, new technology add-on payment start date, the 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, and coding assignments for each technology. We referred readers to the final rules cited in the table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We invited public comments on our proposals to discontinue new technology add-on payments for FY 2023 for the technologies listed in the table in the proposed rule.

Comment: A commenter supported our proposal to discontinue new technology add-on payments for AZEDRA®, which will no longer be considered new as its 3-year anniversary date of entry onto the U.S. market will occur prior to FY 2023.

Response: We appreciate the commenter's support and are finalizing our proposal to discontinue new technology add-on payments for AZEDRA® for FY 2023.

Comment: Many commenters stated their opposition to discontinuing new technology add-on payments for technologies whose 3-year anniversary of entry onto the U.S. market will occur prior to FY 2023 or in the first half of FY 2023. These commenters encouraged CMS to use its legal authority under section 1886(d)(5)(I) of the Act to extend new technology add-on payments through FY 2023 due to a historic decline in utilization during the COVID–19 pandemic.

Response: We thank the commenters for their input. Consistent with the statute and our implementing regulations, a technology is no longer considered as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349). As such, once a technology has been available on the U.S. market for more than 2 to 3 years, we consider the costs to be included in the MS–DRG relative weights regardless of whether the technology's use in the Medicare population has been frequent or infrequent. Therefore, we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new,'' and we are not extending new technology add-on payments for technologies whose 3-year anniversary of entry onto the U.S. market will occur prior to FY 2023 or in the first half of FY 2023. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44975 through 44979) and section II.F.5.b of this FY 2023 final rule for discussion of our policy to allow for a 1-year extension of new technology add-on payments for FY 2022 because of the unique circumstances associated with ratesetting for FY 2022, for which CMS used FY 2019 data instead of FY 2020 data to develop the FY 2022 relative weights.

Comment: Several commenters disagreed with CMS's proposal to discontinue new technology add-on payments for EXALT Model D™ Single-Use Duodenoscope while continuing payments for aScope® Duodeno through FY 2023 based on the different FDA clearance dates for the two technologies. These commenters recommended that CMS create a single newness date and extend new technology add-on payments for both products through the end of FY 2023. The commenters noted that there is no mechanism for hospitals to distinguish between the two devices when reporting claims to CMS, as the duodenoscopes share one add-on payment amount and are identified using the same ICD–10–PCS codes.

Another commenter, the applicant for EXALT Model D™, stated that creating a single newness date and discontinuation date for a combined new technology add-on payment is consistent with prior CMS decision-making regarding substantially similar technologies such as IMFINZI® and TECENTRIQ® from the FY 2021 IPPS final rule, and the LUTONIX® and IN.PACT™ Admiral™ drug-coated balloons in the FY 2016 IPPS final rule. The commenter noted that, in these instances, CMS finalized the proposal to discontinue the new technology add-on payment for both technologies on the same date and calculated a case-weighted average cost resulting in the same maximum add-on payment for both technologies. The commenter further noted that CMS determined the drug-coated balloons were identifiable using the same ICD–10–PCS procedure codes, and that IMFINZI® and TECENTRIQ® received a one-year extension through FY 2022 based on CMS' decision to use FY 2019 data (instead of FY 2020 data) for the FY 2022 IPPS rate setting. The commenter requested that CMS discontinue the new technology add-on payments for both EXALT Model D™ and aScope™ Duodeno at the same time, preferably at the end of FY 2023. As an alternative, the applicant recommended that CMS recalculate the maximum payment amount from the current case-weighted average of $1,715 per case to reflect 65% of the cost of aScope™ Duodeno only.

Response: We thank the commenters for their input. As stated previously, a technology is no longer considered ''new'' once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349). As such, once a technology has been available on the U.S. market for more than 2 to 3 years, we consider the costs to be included in the MS–DRG relative weights regardless of whether the technology's use in the Medicare population has been frequent or infrequent. Additionally, we note that under § 412.87(c), applications received for new technology add-on payments for FY 2021 and subsequent fiscal years for medical devices that are part of FDA's Breakthrough Devices Program and received FDA marketing authorization will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS. Because EXALT Model D™ and aScope™ Duodeno both applied under the alternative pathway for transformative new technologies, the applicant's comparison to IMFINZI® and TECENTRIQ® from the FY 2021 IPPS final rule (85 FR 58672 through 58684), and the LUTONIX® and IN.PACT™ Admiral™ drug-coated balloons in the FY 2016 IPPS final rule (80 FR 49461 through 49470), where the technologies were determined to be substantially similar and therefore had the same newness period, is not relevant. Thus, we are finalizing our proposal to discontinue new technology add-on payment for EXALT™ Model D™ for FY 2023.

We agree with the applicant's alternative recommendation that the maximum new technology add-on payment amount should reflect the cost of aScope™ Duodeno only. Based on information provided in its application for FY 2022 new technology add-on payment, the cost of the aScope™ Duodeno is $1,995. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the aScope™ Duodeno would be $1,296.75 for FY

2022 (that is, 65% of the average cost of the technology). Cases involving the use of aScope™ Duodeno will continue to be identified by the following ICD–10–PCS procedure codes: XFJB8A7 (Inspection of hepatobiliary duct using single-use duodenoscope, new technology group 7) or XFJD8A7 (Inspection of pancreatic duct using single-use duodenoscope, new technology group).

After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for the technologies as listed in the proposed rule and in the following Table II.F.-02 of this final rule for FY 2023 because they are no longer ''new'' for purposes of new technology add-on payments. This table also presents the newness start date, new technology add-on payment start date, the 3-year anniversary date of the product's entry onto the U.S. market, and relevant final rule citations from prior fiscal years. We also refer readers to the final rules cited in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

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TABLE II.F.-02: DISCONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2022 NEW TECHNOLOGY ADD-ON PAYMENTS NO LONGER CONSIDERED NEW FOR FY 2023 BECAUSE 3-YEAR ANNIVERSARY DATE WILL OCCUR PRIOR TO APRIL 1, 2023

	Technology	FDA/Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto US Market	Previous Final Rule Citations
1	*Balversa™*	*04/12/2019*	*10/19/2019*	*4/12/2022*	84 FR 42237 through 42242 85 FR 58616 86 FR 44972 through 44974
2	*Jakafi®*	*05/24/2019*	*10/1/2019*	*5/24/2022*	84 FR 42265 through 42273 85 FR 58617 through 58618 86 FR 44973 through 44974
3	*BAROSTIM NEO™ System*	*08/16/2019*	*10/1/2020*	*08/16/2022*	85 FR 58716 through 58717 86 FR 44973 through 44974 86 FR 67874 through 67876
4	*Optimizer® System*	*10/23/2019*	*10/1/2020*	*10/23/2022*	85 FR 58720 through 58721 86 FR 44973 through 44974
5	*RECARBRIO™ (cUTI/ cIAI)*	*07/16/2019 commercially available in US 1/6/20*	*10/1/2020*	*1/6/2023*	85 FR 58727 through 58729 86 FR 44973 through 44974 86 FR 67874 through 67876
6	*Soliris®*	*06/27/2019*	*10/1/2020*	*6/27/2022*	85 FR 58684 through 58689 86 FR 44973 through 44975
7	*XENLETA™*	*08/19/2019 commercially available in US 9/10/19*	*10/1/2020*	*9/10/2022*	85 FR 58729 through 58732 86 FR 44973 through 44975
8	*ZERBAXA®*	*06/03/2019*	*10/1/2020*	*6/03/2022*	85 FR 58732 through 58733 86 FR 44973 through 44975
9	*Azedra®*	*05/21/2019*	*10/1/2019*	*5/21/2022*	84 FR 42194 through 42201 85 FR 58615 86 FR 44973 through 44975
10	*EXALT™ Model D*	*12/13/2019*	*10/1/2021*	*12/13/2022*	86 FR 45138 through 45140
11	*Fetroja® (Cefiderocol)* (cUTI)	*11/19/2019 Commercially available in US 2/24/2020*	*10/1/2020*	*2/24/2023*	85 FR 58721 through 58723 86 FR 44973 through 44974 86 FR 67876

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b. Status of Technologies Provided a One-Year Extension of New Technology Add-On Payments in FY 2022

As stated in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44789), our goal is always to use the best available data overall for ratesetting. The best available MedPAR data will typically be the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking.

In the FY 2022 IPPS/LTCH PPS final rule, for the reasons discussed, we finalized that we would use FY 2019 MedPAR data instead of FY 2020 MedPAR data to develop the FY 2022 MS–DRG relative weights (86 FR 44789 through 44793). Because we finalized that we would use FY 2019 MedPAR data instead of FY 2020 MedPAR data for the development of the FY 2022 MS–DRG relative weights, we stated that the costs for a new technology for which the 3-year anniversary date of the product's entry onto the U.S. market occurs prior to the latter half of FY 2022 may not be fully reflected in the MedPAR data used to recalibrate the MS–DRG relative weights for FY 2022. Therefore, in light of this final policy, we finalized our proposal to use our authority under section 1886(d)(5)(I) of the Act to allow for a 1-year extension of new technology add-on payments for FY 2022 for 13 technologies (as listed in the proposed rule and in Table II.F.-03 of this final rule) for which the new technology add-on payment would have otherwise been discontinued beginning with FY 2022. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44975 through 44979) for a complete discussion regarding this 1-year extension for FY 2022.

For FY 2023 ratesetting, as discussed in section I.F. of this final rule, we believe the best available data is the FY 2021 MedPAR file. As discussed in section I.F. of this final rule, for FY 2023, we are finalizing our proposal to use the FY 2021 MedPAR (the best available data at the time of this final rule) for FY 2023 ratesetting, including for purposes of developing the FY 2023 relative weights. We refer the reader to section I.F. of this final rule for a complete discussion regarding our final policy to use the FY 2021 MedPAR for the FY 2023 ratesetting and recalibration of the FY 2023 MS–DRG relative weights.

As noted previously, our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. For FY 2023, because we proposed to use FY 2021 MedPAR data to recalibrate the FY 2023 MS–DRG relative weights, we stated in the proposed rule that we believe the costs of the 13 technologies as listed in the proposed rule (87 FR 28216 through 28217) and in Table II.F.-03 of this final rule, for which the 3-year anniversary date of the product's entry onto the U.S. market occurs prior to FY 2023 (and therefore are no longer ''new''), may now be fully reflected in the MedPAR data used to recalibrate the MS–DRG relative weights for FY 2023. As a result, we proposed to discontinue new technology add-on payments for these 13 technologies in FY 2023. We also refer readers to the final rules cited in Table II.F.-03 for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We invited public comments on our proposals to discontinue new technology add-on payments for FY 2023 for these 13 technologies listed in the proposed rule and Table II.F.–03.

Comment: Many commenters, including several applicants for technologies currently receiving new technology add-on payments, stated their opposition to discontinuing new technology add-on payments for technologies that received a one-year extension in FY 2022. These commenters stated that the FY 2021 MedPAR claims data are distorted due to effects of the COVID–19 pandemic and should not be used to recalibrate the MS–DRG relative weights. The commenters encouraged CMS to use its legal authority under section 1886(d)(5)(I) of the Act to extend new technology add-on payments through FY 2023.

Another commenter stated that while it is accurate that the costs of the technologies are reflected in the FY 2021 MedPAR data used for ratesetting purposes, the existence of such claims data does not mean that the costs of the technology are truly captured, nor does it mean that the pandemic has not impacted adoption of the new technologies and services. This commenter referenced several studies to demonstrate the impact of the PHE on hospitals, including critical staff shortages and financial instability due to lower revenues and inflation. The commenter also provided an analysis of FY 2021 claims data that found that the average standardized costs when accounting for cases using its technology or comparable technology reported under the same ICD–10–PCS codes increased by less than 0.5% compared to average standardized costs that do not account for cases reported under these codes.

Response: We thank the commenters for their input. Consistent with the statute and our implementing regulations, a technology is no longer considered as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349). As such, once a technology has been available on the U.S. market for more than 2 to 3 years, we consider the costs to be included in the MS–DRG relative weights regardless of whether the technology's use in the Medicare population has been frequent or infrequent. Therefore, we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new''. Additionally, as previously discussed, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44975 through 44979), we finalized a 1-year extension of new technology add-on payments for FY 2022 in light of the unique circumstances associated with ratesetting for FY 2022, for which CMS finalized the use of the FY 2019 MedPAR data instead of the FY 2020 MedPAR data to develop the FY 2022 relative weights. For FY 2023, because we are finalizing the use of the FY 2021 MedPAR data for FY 2023 ratesetting, including for purposes of developing the FY 2023 relative weights, we believe the costs of these technologies are now reflected in the MedPAR data used to recalibrate the MS–DRG relative weights for FY 2023. Therefore, we are not extending new technology add-on payments for technologies that received a one-year extension in FY 2022. We refer readers to sections section I.F. and II.E. of this final rule for discussion of CMS's finalized policy to use the FY 2021 MedPAR claims data to recalibrate the FY 2023 MS–DRG relative weights, including the finalized modifications to the relative weight setting methodology to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals as compared to FY 2021.

After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for the technologies as listed in the proposed rule and in the following Table II.F.-03 of this final rule for FY 2023. This table also presents the

newness start date, new technology add-on payment start date, the 3-year anniversary date of the product's entry onto the U.S. market, and relevant final rule citations from prior fiscal years. We also refer readers to the final rules cited in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

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TABLE II.F.-03: DISCONTINUATION OF TECHNOLOGIES WHICH RECEIVED A ONE YEAR EXTENSION FOR NEW TECHNOLOGY ADD-ON PAYMENT IN FY 2022 BECAUSE 3-YEAR ANNIVERSARY DATE OCCURRED BEFORE THE SECOND HALF OF FY 2022

Technology		FDA/Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto US Market	Previous Final Rule Citations
1	*Cablivi®*	*02/06/2019*	*10/01/2019*	*02/06/2022*	84 FR 42201 through 42208 85 FR 58615 86 FR 44975 through 44979
2	*Elzonris™*	*12/21/2018*	*10/01/2019*	*12/21/2021*	84 FR 42231 through 42237 85 FR 58615 through 58616 86 FR 44975 through 44979
3	*AndexXa™*	*05/03/2018*	*10/01/2018*	*05/03/2021*	83 FR 41355 through 41362 84 FR 42193 through 42194 85 FR 58614 through 58615 86 FR 44975 through 44979
4	*Spravato®*	*3/5/2019*	*10/01/2019*	*3/5/2022*	84 FR 42247 through 42256 85 FR 58616 through 58617 86 FR 44975 through 44979
5	*Zemdri®*	*6/25/2018*	*10/01/2018*	*6/25/2021*	83 FR 41326 through 41334 84 FR 42190 through 42191 85 FR 58613 86 FR 44975 through 44979
6	*T2 Bacteria® Panel*	*05/24/2018*	*10/01/2019*	*05/24/2021*	84 FR 42278 through 42288 85 FR 58618 86 FR 44975 through 44979
7	*ContaCT*	*02/13/2018 (commercially available 10/01/2018)*	*10/01/2020*	*10/01/2021*	85 FR 58625 through 58636 86 FR 44975 through 44979
8	*Eluvia™ Drug-Eluting Vascular Stent System*	*09/18/2018 commercially available in US 10/04/2018*	*10/01/2020*	*10/04/2021*	85 FR 58645 through 58658 86 FR 44975 through 44979
9	*Hemospray®*	*05/07/2018 (commercially available 07/01/2018)*	*10/01/2020*	*07/01/2021*	85 FR 58665 through 58672 86 FR 44975 through 44979
10	*IMFINZI®/ TECENTRIQ®*	*IMFINZI®: 03/27/2020; TECENTRIQ®: 03/18/2019 Newness date is 3/18/2019 for both*	*10/01/2020*	*03/18/2022*	85 FR 58672 through 58684 86 FR 44975 through 44979
11	*NUZYRA®*	*10/02/2018 (commercially available 02/01/2019)*	*10/01/2020*	*2/01/2022*	85 FR 58725 through 58727 86 FR 44975 through 44979
12	*SpineJack® System*	*08/30/2018 (commercially available 10/11/2018)*	*10/01/2020*	*10/11/2021*	85 FR 58689 through 58701 86 FR 44975 through 44979
13	Xospata®	11/28/2018	10/01/2019	11/28/2021	84 FR 42256 through 42260 85 FR 58617 86 FR 44975 through 44979

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6. FY 2023 Applications for New Technology Add-On Payments (Traditional Pathway)

We received 18 applications for new technology add-on payments for FY 2023 under the traditional new technology add-on payment pathway. In accordance with the regulations under § 412.87(e), applicants for new technology add-on payments must have received FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Five applicants withdrew their applications prior to the issuance of the proposed rule. Subsequently, seven applicants withdrew their respective applications for lifileucel, narsoplimab, TERLIVAZ (terlipressin), teclistamab, mosunetuzumab, XENOVIEW, and treosulfan prior to the issuance of this FY 2023 IPPS/LTCH PPS final rule. In addition, in accordance with § 412.87(c), applicants for new technology add-on payments must have FDA approval or clearance by July 1 of each year prior to the beginning of the fiscal year for which the application is being considered. One applicant, Boehringer Ingelheim Pharmaceuticals, Inc., for spesolimab, did not receive FDA approval for its technology by July 1, 2022. Therefore, spesolimab is not eligible for consideration for new technology add-on payments for FY 2023. Consistent with our standard approach, we are not including in this final rule the description and discussion of applications that were withdrawn or that are ineligible for consideration for FY 2023 due to not meeting the July 1 deadline, described previously, which were included in the FY 2023 IPPS/LTCH PPS proposed rule. We are also not summarizing nor responding to public comments received regarding these withdrawn or ineligible applications in this final rule. A discussion of the five remaining applications is presented below.

a. CARVYKTI™ (Ciltacabtagene Autoleucel)

Janssen Biotech, Inc., submitted an application for new technology add-on payments for CARVYKTI™ (ciltacabtagene autoleucel) for FY 2023. CARVYKTI™ is an autologous chimeric-antigen receptor (CAR) T-cell therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma. We note that Janssen Biotech, Inc. previously submitted an application for new technology add-on payments for CARVYKTI™ for FY 2022 under the name ciltacabtagene autoleucel, as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 25233 through 25239), but withdrew that application prior to the issuance of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44979).

The applicant stated that ciltacabtagene autoleucel refers to both JNJ–4528, an investigational BCMA-directed CAR T-cell therapy for previously treated patients with multiple myeloma, and LCAR–B38M, the investigational product (ciltacabtagene autoleucel) being studied in China. Both JNJ–4528 and LCAR–B38M are representative of the same CAR T-cell therapy, ciltacabtagene autoleucel.

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells.[32] Plasma cells, found in bone marrow, make the antibodies that help the body attack and kill various pathogens. According to the applicant, when damaged, malignant plasma cells rapidly spread and replace the normal cells in the bone marrow.[33] The applicant asserted the median age of onset is 69 years old and only 3% of patients are less than 45 at the age of diagnosis; it was estimated that in 2021 nearly 35,000 people would be diagnosed and more than 12,000 will die from multiple myeloma in the US.[34] According to the applicant, multiple myeloma is associated with substantial morbidity and mortality[35] and median 5 year survival is 56%.[36]

According to the applicant, introduction of new treatment options in the last 2 decades has extended the median survival of multiple myeloma patients. The applicant asserted that the introduction of proteasome inhibitors (PI) (for example, bortezomib, carfilzomib, and ixazomib), histone deacetylase inhibitors (for example, panobinostat, vorinostat), immunomodulatory agents (IMiD) (for example, thalidomide, lenalidomide, and pomalidomide), monoclonal antibodies (daratumumab and elotuzumab), and stem cell transplantation, have allowed numerous therapeutic options for patients with multiple myeloma (Rajkumar 2020). According to the applicant, the National Comprehensive Cancer Network (NCCN) recommended treatment regimen for first-line therapy of multiple myeloma is bortezomib (a PI), lenalidomide (an IMiD) and dexamethasone.[37] According to the applicant, the strategy of triplet therapies for patients with newly diagnosed multiple myeloma, followed by high-dose chemotherapy and autologous stem-cell transplantation for eligible patients, and subsequently consolidation and maintenance therapy, is the current treatment roadmap for patients.[38] However, despite these treatments, according to the applicant, most patients will relapse after first-line treatment and require further treatment[39] with only 50% survival of relapsed patients after 5 years.[40] [41] The applicant stated that as multiple myeloma progresses, each subsequent line of treatment is associated with shorter progression free survival (PFS) and decreased rate, depth, and durability of response and worsening of quality of life.[42] In addition, cumulative and long-term toxicities are often associated with long-term therapy (Ludwig, 2018). Thus, according to the applicant, there remains an ongoing need for additional therapeutic approaches when the disease is resistant to available therapy.

The applicant asserted that relapsed and refractory (r/r) multiple myeloma (RRMM) constitutes a specific unmet medical need. According to the applicant, patients with r/r disease are defined as those who, having achieved

[32] Ho, M., Chen, T., Liu, J. et al. Targeting histone deacetylase 3 (HDAC3) in the bone marrow microenvironment inhibits multiple myeloma proliferation by modulating exosomes and IL–6 trans-signaling. Leukemia 34, 196–209 (2020). *https://doi.org/10.1038/s41375-019-0493-x.*

[33] Utley A, Lipchick B, Lee KP, Nikiforov MA. Targeting Multiple Myeloma through the Biology of Long-Lived Plasma Cells. Cancers (Basel). 2020 Jul 30;12(8):2117.

[34] Surveillance, Epidemiology, and End Results (SEER) Program. SEER database 2020; *https://seer.cancer.gov/statfacts/html/mulmy.html.*

[35] Cowan AJ, Allen C, Barac A, Basaleem H, Bensenor I, Curado MP, Foreman K, Gupta R, Harvey J, Hosgood HD, Jakovljevic M, Khader Y, Linn S, Lad D, Mantovani L, Nong VM, Mokdad A, Naghavi M, Postma M, Roshandel G, Shackelford K, Sisay M, Nguyen CT, Tran TT, Xuan BT, Ukwaja KN, Vollset SE, Weiderpass E, Libby EN, Fitzmaurice C. Global Burden of Multiple Myeloma: A Systematic Analysis for the Global Burden of Disease Study 2016. JAMA Oncol. 2018 Sep 1;4(9):1221–1227.

[36] SEER database 2020; *https://seer.cancer.gov/statfacts/html/mulmy.html.*

[37] National Comprehensive Cancer Network (NCCN) NCCN clinical practice guidelines in oncology. Multiple Myeloma. Version 2. 2021—September 9, 2020.

[38] Branagan A, Lei M, Lou U, Raje N. Current Treatment Strategies for Multiple Myeloma. JCO Oncol Pract. 2020 Jan;16(1):5–14.

[39] Sonneveld P, Broij lA. Treatment of relapsed and refractory multiple myeloma. Haematologica. 2016;101(4):396–406.

[40] SEER database 2020; *https://seer.cancer.gov/statfacts/html/mulmy.html.*

[41] Global Cancer Observatory. GLOBOCAN database 2018; *https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf.*

[42] Yong K, Delforge M, Driessen C, Fink L, Flinois A, Gonzalez-McQuire S, Safaei R, Karlin L, Mateos MV, Raab MS, Schoen P, Cavo M. Multiple myeloma: patient outcomes in real-world practice. Br J Haematol. 2016 Oct;175(2):252–264.

a minor response or better, relapse and then progress while on therapy, or experience progression within 60 days of their last therapy.[43] [44] The applicant stated the introduction of a new class of agents, CD38-targeting monoclonal antibodies (CD38 MoAbs), daratumumab and isatuximab, have improved options in r/r patients.[45] The applicant asserted that given these advances, guideline recommendations following first-line therapy are varied, with treatment options including combinations of novel agents with existing standard of care regimens, and include triplet and quadruplet regimens, creating a complex treatment landscape.[46] According to the applicant, while triplet regimens should be used as the standard therapy for patients with multiple myeloma, elderly or frail patients may be treated with double regimens.[47] The applicant further stated that for patients with RRMM who have received at least three prior lines of therapy, including a PI, an IMiD and an anti-CD38, there does not exist a standard or consensus for treatment at this time, and often, supportive care/palliative care is the only option.[48]

According to the applicant, multiple myeloma remains incurable and most patients eventually relapse, even with the advent of new treatments.[49] The applicant further stated that novel, innovative therapies are needed to improve long-term survival and outcomes. The applicant asserted that CAR T-cell-based therapies offer potential advantages over current therapeutic strategies. According to the applicant, while other therapies require long-term repetitive administration generally until progression of disease, CAR T-cell therapy is a single infusion treatment due to live T-cell expansion in the patient and long-term disease response. The applicant asserted that CARVYKTI™ is an autologous CAR T-cell therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma. The applicant stated that BCMA, a protein that is highly expressed on myeloma cells[50] and is a member of the tumor necrosis factor (TNF) receptor family, plays a central role in regulating B-cell maturation and differentiation into plasma cells.[51] [52] The applicant stated BCMA is selectively expressed on a subset of B cells (plasma cell neoplasms including myeloma cells) and is more stably expressed specifically on the B cell lineage, compared with key plasma cell marker CD138, which is also expressed on normal fibroblasts and epithelial cells.[53] [54] [55] According to the applicant, these expression characteristics make BCMA an ideal therapeutic target for the treatment of multiple myeloma.[56] [57] CARVYKTI™, according to the applicant, is a unique, structurally differentiated BCMA-targeting chimeric antigen receptor with two distinct BCMA-binding domains that can identify and eliminate myeloma cells.

The applicant asserted that CAR T-cell technology is a form of immunotherapy and is a ''living drug'' that utilizes specially altered T cells, part of the immune system, to fight cancer. According to the applicant, a sample of the patient's T cells are collected from the blood, then modified in a laboratory setting to express a CAR.[58] The applicant stated chimeric antigen receptors are specifically designed receptor proteins that are made up of three distinct features: (1) a target recognition domain (typically derived from a single domain of an antibody) that sits on the cell's exterior; (2) a co-stimulatory domain on the cell's interior that boosts activation, enhances survival and expansion of the modified cells; and (3) an interior stimulatory domain that supports activation and target killing.[59] According to the applicant, the binding domain expressed on the surface of T cells gives them the new ability to target a specific protein. The applicant stated, when the target is recognized, the intracellular portions of the receptor send signals within the T cells to destroy the target cells. The applicant asserted these engineered CAR T-cells are reinfused back into the same patient, which enables these specialized T cells to latch onto the target antigen and abolish the tumor cells.

According to the applicant, CARVYKTI™ is a CAR T-cell immunotherapy designed to recognize myeloma cells and target their destruction. According to the applicant, CARVYKTI™'s CAR T-cell technology consists of harvesting the patient's own T cells, programming them to express a chimeric antigen receptor that identifies BCMA, a protein highly expressed on the surface of malignant multiple myeloma B-lineage cells, and reinfusing these modified cells back into the patient where they bind to and eliminate myeloma tumor cells. The applicant asserted that, unlike the chimeric antigen receptor design of currently approved CAR T-cell immunotherapies, which are composed of a single-domain antibody (sdAbs), CARVYKTI™ is composed of two antibody binding domains that allow for high recognition of human BCMA (CD269) and elimination of BCMA expressing myeloma cells. According to the applicant, the two distinct BCMA-binding domains confer avidity and distinguish CARVYKTI™ from other BCMA-targeting products. The applicant stated the BCMA binding domains are linked to the receptor's interior costimulatory (4–1BB) and signaling (CD3ζ) domains through a transmembrane linker (CD8a). The applicant asserted these intracellular domains are critical components for T cell growth and anti-tumor activity[60] in the body once CAR T-cells are bound to a BCMA target on multiple myeloma cells.

[43] Castelli R, Orofino N, Losurdo A, Gualtierotti R, Cugno M. Choosing treatment options for patients with relapsed/refractory multiple myeloma. Expert Rev Anticancer Ther. 2014 Feb;14(2):199–215.

[44] Nooka AK, Kastritis E, Dimopoulos MA, Lonial S. Treatment options for relapsed and refractory multiple myeloma. Blood. 2015 May 14;125(20):3085–99.

[45] Van de Donk NWCJ, Richardson PG, Malavasi F. CD38 antibodies in multiple myeloma: back to the future. Blood. 2018 Jan 4;131(1):13–29.

[46] National Comprehensive Cancer Network (NCCN) NCCN clinical practice guidelines in oncology. Multiple Myeloma. Version 2. 2021—September 9, 2020.

[47] Ibid.

[48] Maples KT, Joseph NS, Harvey RD. Current developments in the combination therapy of relapsed/refractory multiple myeloma. Expert Rev Anticancer Ther. 2020 Sep 24.

[49] Rajkumar SV, Kumar S. Multiple myeloma current treatment algorithms. Blood Cancer J. 2020 Sep 28;10(9):94.

[50] Cho SF, Anderson KC, Tai YT. Targeting B Cell Maturation Antigen (BCMA) in Multiple Myeloma: Potential Uses of BCMA-Based Immunotherapy. Front Immunol. 2018 Aug 10;9:1821.

[51] Cho SF, Anderson KC, Tai YT. Targeting B Cell Maturation Antigen (BCMA) in Multiple Myeloma: Potential Uses of BCMA-Based Immunotherapy. Front Immunol. 2018 Aug 10;9:1821.

[52] Tai YT, Anderson KC. Targeting B-cell maturation antigen in multiple myeloma. Immunotherapy. 2015;7(11):1187–99.

[53] Cho SF, Anderson KC, Tai YT. Targeting B Cell Maturation Antigen (BCMA) in Multiple Myeloma: Potential Uses of BCMA-Based Immunotherapy. Front Immunol. 2018 Aug 10;9:1821.

[54] Tai YT, Anderson KC. Targeting B-cell maturation antigen in multiple myeloma. Immunotherapy. 2015;7(11):1187–99.

[55] Palaiologou M, Delladetsima I, Tiniakos D. CD138 (syndecan-1) expression in health and disease. Histol Histopathol. 2014 Feb;29(2):177–89.

[56] Ibid.

[57] Frigyesi I, Adolfsson J, Ali M, Christophersen MK, Johnsson E, Turesson I, Gullberg U, Hansson M, Nilsson B. Robust isolation of malignant plasma cells in multiple myeloma. Blood. 2014 Feb 27;123(9):1336–40.

[58] June CH, Sadelain M. Chimeric Antigen Receptor Therapy. N Engl J Med. 2018 Jul 5;379(1):64–73.

[59] Sadelain M. Chimeric antigen receptors: driving immunology towards synthetic biology. Curr Opin Immunol. 2016 Aug;41:68–76.

[60] Maher J, Brentjens RJ, Gunset G, Rivière I, Sadelain M. Human T-lymphocyte cytotoxicity and proliferation directed by a single chimeric TCRzeta/CD28 receptor.

With respect to the newness criterion, according to the applicant, CARVYKTI™ was granted Breakthrough Therapy designation in December 2019 for the treatment of adult patients with relapsed or refractory multiple myeloma, who previously received a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody. Per the applicant, FDA approved the Biologics License Application (BLA) for CARVYKTI™ on February 28, 2022 for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. The applicant stated that procedures involving the administration of CARVYKTI™ can be uniquely identified using the following ICD–10–PCS procedure codes: XW033A7 (Introduction of ciltacabtagene autoleucel into peripheral vein, percutaneous approach, new technology group 7) or XW043A7 (Introduction of ciltacabtagene autoleucel into central vein, percutaneous approach, new technology group 7). The applicant also noted that they will submit a request for a Healthcare Common Procedure Coding System (HCPCS) code specific to the administration of CARVYKTI™ once the product is eligible for such a code.

As previously stated, if a technology meets all three of the substantial similarity criteria as previously described, it would be considered substantially similar to an existing technology and therefore would not be considered ''new'' for purposes of new technology add-on payments.

With respect to whether a product uses the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome, the applicant asserted that CARVYKTI™ has a unique mechanism of action because it has two distinct binding domains that confer avidity to the BCMA antigen, a 4–1BB costimulatory domain and a CD3z signaling domain, whereas other CAR T-cell products have only one target binding domain. The applicant asserted that ABECMA® also targets BCMA, but does so by binding to a single BCMA domain. In addition to detail provided in the applicant's FY 2022 application (as discussed in 86 FR 25235 through 25236), the applicant asserted that CARVYKTI™ differs significantly from ABECMA® and other BCMA-targeting agents, including Blenrep, because it targets BCMA with two distinct binding domains. According to the applicant, the distinct BCMA-binding moieties confer avidity and distinguish CARVYKTI™ from other BCMA CAR T-cell constructs providing a novel mechanism of action.[61] The applicant added, the 4–1BB and CD3z domains on the CAR optimize T cell activation and proliferation.[62] According to the applicant, non-clinical pharmacology and toxicology have been used to characterize the biological activity and mechanism of action of CARVYKTI™ and confirm the on-target specificity to BCMA through (1) in vitro binding characterization; (2) in vitro co-culture assays to assess CAR T-cell cytotoxicity and cytokine release; (3) in vivo efficacy studies in mice with human CAR T-cells; and (4) an in vivo safety study. According to the applicant, because CARVYKTI™ has a novel mechanism of action with two distinct BCMA-binding domains that confer binding avidity and unprecedented clinical activity compared with other novel anti-myeloma treatments in comparable study populations, it is unlike any existing technology utilized to treat relapsed/refractory multiple myeloma.

With regard to whether a product is assigned to the same DRG when compared to an existing technology, the applicant asserted that because CMS has suggested that all inpatient hospitalizations involving a CAR T-cell treatment will be assigned to DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies), CARVYKTI™ is expected to be assigned to the same DRG as other multiple myeloma cases treated with a CAR T-cell therapy. We note that the DRG assignment was finalized to Pre-MDC MS–DRG 018, effective October 1, 2022 and is reflected in the V39.1 ICD–10 MS–DRG Grouper effective April 1, 2022 (86 FR 58021).[63]

With regard to whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant asserted in its application that CARVYKTI™ is indicated for a broader population than other available therapies, specifically multiple myeloma patients having received three prior therapies. The applicant asserted in its application that Blenrep and ABECMA® are indicated only for those with at least 4 prior therapies whereas CARVYKTI™ had a proposed indication for the treatment of patients with 3 or more prior therapies. According to the applicant, CARVYKTI™ could potentially be used in a broader multiple myeloma population, that includes patients after 3 prior therapies as opposed to 4 for Blenrep and ABECMA®.

According to the applicant, in the registrational trial CARTITUDE 1, 17% (a total of 17 patients) of patients had only three prior lines of therapy; results were presented at the American Society of Hematology (ASH) 2021 meeting on fourth line patients. The applicant stated that among those with three prior lines of therapy, the response rate was 100%, the median duration of response (DoR) was 21.8 months, minimal residual disease (MRD) negativity was found in 80%, the 18-month progression free survival (PFS) was 75.6%, and the 18-month overall survival (OS) was 88.2 months. According to the applicant, because the sample size was small (17), median endpoints may not be as rigorous as in the larger population.

According to the applicant, the distinction between three and four previous lines of therapy is important. The applicant asserted with each subsequent therapy patients generally become frailer and their prognosis worsens. The applicant stated that studies comparing fourth line to fifth line are not as common as trials studying earlier lines, but in a real-world study by Yong et al. the percent of myeloma patients who were able to move from third line therapy to fourth line was 15% of all diagnosed myeloma patients, and only 1% of patients moved to a fifth line.[64] The applicant added that in the same study of those patients in first line therapy, approximately 90% of patients were able to discontinue treatment due to remission and/or planned end of treatment while only 13% of those in fifth line ended treatment due to stable disease/remission.

The applicant asserted that for these reasons, CARVYKTI™ does not meet the third criterion and is therefore a new technology with regards to the

[61] Xu J, Chen LJ, Yang SS, Sun Y, Wu W, Liu YF, Xu J, Zhuang Y, Zhang W, Weng XQ, Wu J, Wang Y, Wang J, Yan H, Xu WB, Jiang H, Du J, Ding XY, Li B, Li JM, Fu WJ, Zhu J, Zhu L, Chen Z, Fan XF, Hou J, Li JY, Mi JQ, Chen SJ. Exploratory trial of a biepitopic CAR T-targeting B cell maturation antigen in relapsed/refractory multiple myeloma. Proc Natl Acad Sci U S A. 2019 May 7;116(19):9543–9551.

[62] Weinkove R, George P, Dasyam N, McLellan AD. Selecting costimulatory domains for chimeric antigen receptors: functional and clinical considerations. Clin Transl Immunology. 2019 May 11;8(5):e1049.

[63] CMS Manual System, Pub. 100–04 Medicare Claims Processing, Transmittal 11255. February 4, 2022; *https://www.cms.gov/files/document/r11255cp.pdf.*

[64] Yong et al. 2016. Multiple Myeloma: Patient outcomes in real-world practice. *British Journal of Haematology,* 175; 252–264. doi: 10.1111/bjh.14213.

population having been studied and being targeted for use.

In summary, the applicant asserted that CARVYKTI™ meets the newness criterion because it is not substantially similar to other available therapies due to its unique mechanism of action, with two distinct binding domains that confer avidity to the BCMA antigen, and because it treats a different patient population, RRMM patients who received three prior therapies.

In the FY 2023 IPPS/LTCH PPS proposed rule, as stated in the FY 2022 proposed rule (86 FR 25236), we noted that CARVYKTI™ may have a similar mechanism of action to that of ABECMA®. We also noted that ABECMA® received approval for new technology add-on payments for FY 2022 for the treatment of adult patients with RRMM after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody (86 FR 45028 through 45035). We stated that although the number of BCMA binding domains of CARVYKTI™ and ABECMA® differ, it appeared that the mechanism of action for both therapies is the binding to BCMA by a CAR construct, which results in T-cell activation and killing of malignant myeloma cells. We noted that the applicant asserted that CARVYKTI™'s mechanism of action is unique due to its dual binding domain which affects the therapy's clinical activity, as compared to existing technologies with a single binding domain. However, we were unclear as to how the additional BCMA binding domain represents a change in the mechanism of action of this therapy, or if it may instead relate to an assessment of whether the technology meets the substantial clinical improvement criterion. Because of the potential similarity with the BCMA antigen and other actions, we stated our belief that the mechanism of action for CARVYKTI™ may be the same or similar to that of ABECMA®.

We also noted that the applicant stated that CARVYKTI™ may serve a new patient population if approved as a fourth line treatment, as existing treatments are approved for fifth line treatment. However, because CARVYKTI™'s recent approval stated that it is indicated for fifth line treatment, we questioned whether CARVYKTI™ treats a new patient population.[65]

Accordingly, as it appeared that CARVYKTI™ and ABECMA® are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action, are assigned to the same MS–DRG, and treat the same or similar patient population and disease, we stated our belief that these technologies may be substantially similar to each other. We noted that if this technology is substantially similar to ABECMA®, we believe the newness period for this technology would begin on March 26, 2021, the date ABECMA® received FDA approval. We expressed our interest in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion. We invited public comment on whether CARVYKTI™ meets the newness criterion, including whether CARVYKTI™ is substantially similar to ABECMA® for purposes of new technology add-on payments.

Comment: Several commenters voiced their support for CARVYKTI™ in their general comments supporting all CAR T-cell therapies. The commenters encouraged CMS to consider approving the new technology add-on payment for new CAR T-cell therapies, including CARVYKTI, as they stated this encourages hospitals to adopt breakthrough technologies by helping them recover some of the increased costs associated with offering innovative treatments to patients.

Response: We thank the commenters for their support.

Comment: The applicant submitted a comment in response to concerns raised by CMS in the proposed rule, reiterating that CARVYKTI™ meets the newness criterion and is not substantially similar to ABECMA® and other multiple myeloma treatments. The applicant stated that, while both CARVYKTI™ and ABECMA® are CAR T-cell therapies directed against BCMA for the treatment of patients with multiple myeloma, there are mechanistic differences that contribute to a different CAR T-cell dose, pharmacokinetic/pharmacodynamic profile, and a different time frame for the development of cytokine release syndrome (CRS) as compared to ABECMA®'s single binding domain. The applicant presented the following table outlining the key scientific differences between CARVYKTI™ and ABECMA®.

[65] *https://www.fda.gov/media/156572/download.*

Key Scientific Differences Between CARVYKTI™ and ABECMA®		
	CARVYKTI™	ABECMA®
BCMA Binding Domain	Double	Single
Dosage	0.75 x 10^6 CAR-positive viable T cells	300 to 400 x 10^6
Expansion of T cell populations	CD8 central memory cells	CD4 cells
Onset of CRS	Day 7	Day 1
IL-6	Peaks at day 10	Peaks at day 5
Peak IL-6, CRS grade 3	~1000 pg/ml.	>10,000 pg/nl
Other cytokines	Return to baseline levels in 2 to 3 months	Return to baseline levels in 1 month

In terms of differences in dosage, the applicant stated the clinical target dose of CARVYKTI™ is 0.75 ×10^6 CAR-positive viable T-cells/kg whereas ABECMA® is 300–400 × 10^6 cells/kg. In terms of differences in expansion of T-cell populations, the applicant stated that CARVYKTI™ has preferential expansion of CD8 T-cells as opposed to CD4 T-cells for ABECMA®. In terms of the differences in pharmacokinetic and pharmacodynamic properties, the applicant stated that the median time to reach maximum expansion for CARVYKTI™ was approximately 13 days after infusion, whereas for ABECMA® it was much sooner. According to the applicant, because of this longer lag time for maximal expansion, the highest peak IL–6 levels is around 10 days for CARVYKTI™ as opposed to 5 days with ABECMA®, which resulted in differences in the side effect profile, as the median time to onset of CRS is 7 days for CARVYKTI™ as opposed to 1 day for ABECMA®. The applicant stated that patients with CRS of Grade 3 severity had IL–6 peak levels of ~1,000 pg/ml with CARVYKTI™ as opposed to over 10,000 pg/ml with ABECMA®. The applicant also stated that the return to baseline levels of IL–6 occurred in 2–3 months for patients treated with CARVYKTI™ as opposed to 1 month with ABECMA®. Lastly, the applicant stated that another important distinction between CARVYKTI™ and ABECMA® was that CARVYKTI™ is derived from llama antibodies directed against BCMA whereas ABECMA® is derived from mouse antibodies. We note that the applicant agreed with our assessment that CARVYKTI™ does not treat a new population.

Another commenter requested that CARVYKTI™ be considered for a separate new technology add-on payment and should not be combined with other new technologies as the commenter considers the newness, cost, and substantial clinical improvement requirements met for CARVYKTI™. Per the commenter, this would ensure the maximum impact for each product for CAR T-cell therapy, which the commenter stated is significantly underpaid.

Response: We appreciate the information submitted by commenters regarding the newness criterion for CARVYKTI™. However, we disagree that CARVYKTI™ has a unique mechanism of action. While the applicant highlighted differences between CARVYKTI™ and ABECMA®, such as number of domains, dosage, time to CRS onset, pharmacokinetic/pharmacodynamic profile, side effects, source of antibodies, and CD4/CD8 ratios, we do not believe these meaningfully differentiate the mechanism of action of CARVYKTI™ from other BCMA-directed CAR T-cell therapies such as ABECMA®, as they are both considered genetically modified autologous T-cell immunotherapies that bind to BCMA-expressing cancer cells.

While CARVYKTI™ has two BCMA binding domains as opposed to one binding domain for ABECMA®, the resulting mechanism of action produces the same therapeutic outcome of CAR expressing CD4 and CD8 T-cells directed against BCMA for the treatment of multiple myeloma. We also disagree with applicant's assertion that CARVYKTI™'s preferential expansion of CD8 T-cells leads to a different mechanism of action, as both CARVYKTI™ and ABECMA® produce a combination of CD4 and CD8 T-cells. While the ratio of these T-cells may vary, it does not substantiate a difference in mechanism of action which, as noted previously, is the targeting of and binding to the BCMA-expressing cancer cells. Lastly, we disagree that a difference in dosage and production represents a different mechanism of action. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44996 through 45000) for a further discussion of this issue, where we determined that BREYANZI® had a similar mechanism of action to KYMRIAH® and YESCARTA®.

After consideration of the comments received, and for the reasons discussed, we believe that CARVYKTI™ and ABECMA® use the same or a similar mechanism of action to achieve a therapeutic outcome, as both products are BCMA-targeting CAR T-cell immunotherapies that result in similar T-cell activation and killing of malignant myeloma cells. Furthermore, as discussed previously, CARVYKTI™ maps to the same MS–DRG and treats the same patient population (those with multiple myeloma after 4 or more prior lines of therapy) as ABECMA® and other CAR T-cell therapies. Accordingly, because CARVYKTI™ meets all three of the substantial similarity criteria, we believe that it is substantially similar to ABECMA®. In

accordance with our policy, because these technologies are substantially similar to each other, we use the earliest market availability date submitted as the beginning of the newness period for both technologies. Therefore, we consider the beginning of the newness period for CARVYKTI® to be March 26, 2021, which is the date that ABECMA® received FDA marketing authorization.

Consistent with our policy statements in the past regarding substantial similarity, we will not be making a determination on cost and substantial clinical improvement for CARVYKTI™. Specifically, we have noted that approval of new technology add-on payments would extend to all technologies that are substantially similar, and if substantially similar technologies are submitted for review in different (and subsequent) years, we evaluate and make a determination on the first application and apply that same determination to the second application (85 FR 58679). Since ABECMA® was approved for new technology add-on payments for FY 2022 and is still within its newness period for FY 2023, and we have determined that CARVYKTI™ is substantially similar to ABECMA®, we apply that same approval for new technology add-on payments to CARVYKTI™. We note that we received public comments with regard to the cost and substantial clinical improvement criteria for this technology, but because the determination made in the FY 2022 IPPS/LTCH PPS final rule for ABECMA® is applied to CARVYKTI™ due to their substantial similarity, we are not summarizing comments received or making a determination on those criteria in this final rule.

Cases involving the use of CARVYKTI™ that are eligible for new technology add-on payments will be identified by procedure codes XW033A7 (Introduction of ciltacabtagene autoleucel into peripheral vein, percutaneous approach, new technology group 7) or XW043A7 (Introduction of ciltacabtagene autoleucel into central vein, percutaneous approach, new technology group 7). In its application, the applicant estimated that the cost of CARVYKTI™ is $465,000.00 per patient. Because CARVYKTI™ is substantially similar to ABECMA®, we believe using a single cost for purposes of determining the new technology add-on payment amount is appropriate for CARVYKTI™ and ABECMA® even though each applicant has its own set of codes. We also believe using a single cost provides predictability regarding the add-on payment when using CARVYKTI™ and ABECMA® for the treatment of patients with RRMM. As such, we believe that the use of a weighted average of the cost of CARVYKTI™ and ABECMA® based upon the projected numbers of cases involving each technology to determine the maximum new technology add-on payment would be most appropriate. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 420 cases (241 plus 179). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case weighted percentages: 57% for CARVYKTI™ and 43% for ABECMA®. We then multiplied the cost per case for the manufacturer specific drug by the case-weighted percentage (0.57 * $465,000 = $265,050 for CARVYKTI™ and 0.43 * $419,500 = $180,385 for ABECMA®). This resulted in a case-weighted average cost of $445,435 for the technology.

Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of CARVYKTI™ or ABECMA® is $289,532.75 for FY 2023.

b. DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)

Janssen Biotech, Inc., submitted an application for new technology add-on payments for DARZALEX FASPRO® for FY 2023. DARZALEX FASPRO® is a combination of daratumumab (a monoclonal CD38-directed cytolytic antibody), and hyaluronidase (an endoglycosidase) indicated for the treatment of light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone (CyBorD) in newly diagnosed patients and is administered through a subcutaneous injection.

According to the applicant, AL amyloidosis is a life-threatening blood disorder caused by increased production of misfolded immunoglobulin light chains by an abnormal proliferation of malignant CD38+ plasma cells. Per the applicant, these deficient immunoglobulin light chains aggregate into highly ordered amyloid fibrils that deposit in tissues, eventually resulting in progressive organ dysfunction and damage due to the toxic effect of the misfolded proteins (proteotoxicity) and the distortion of the normal tissue architecture by the amyloid deposits.[66] The applicant stated that the most frequently affected organs are the heart, kidney, liver, spleen, gastrointestinal tract and nervous system. Per the applicant, patients often have a poor prognosis, and as many as 30% of patients with AL amyloidosis die within the first year after diagnosis. The applicant stated that approximately 4,500 people in the US develop AL amyloidosis each year.[67] The applicant stated that while there were no FDA approved therapies prior to daratumumab, a number of therapies were used clinically to treat AL amyloidosis including combination therapies like cyclophosphamide-bortezomib-dexamethasone (CyBorD), bortezomib-lenalidomide-dexamethasone (VRd), bortezomib-melphalan-dexamethasone (VMd), melphalan-dexamethasone (Md), and bortezomib-dexamethasone (Vd). The applicant further noted that none of these combination regimens are approved for use by FDA in this specific indication.

According to the applicant, DARZALEX FASPRO® is the first and only FDA-approved treatment for patients with AL amyloidosis and is also approved for multiple indications for treatment of patients with multiple myeloma. The applicant stated that the indication for the technology for which it is submitting a new technology add-on payment application is for the treatment of adult patients with AL amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. The applicant noted that DARZALEX FASPRO® is not indicated nor recommended to be used in patients with AL amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB, except in the context of controlled clinical trials.

According to the applicant, DARZALEX FASPRO® is the subcutaneous formulation of daratumumab, which is a human IgG-kappa monoclonal antibody that targets CD38, an enzymatic protein that is uniformly expressed on human plasma cells. Per the applicant, in DARZALEX FASPRO®, daratumumab is co-formulated with recombinant human hyaluronidase (rHuP20), which critically allows daratumumab to be administered in a volume of 15 mL by a 3–5 minute injection under the skin, compared to the 500–1000 mL volume

[66] Merlini et al. Systemic immunoglobin light chain amyloidosis. Nat Rev Dis Primers. 2018; 4:38–19.

[67] Amyloidosis Foundation. AL amyloidosis facts. *http://www.amyloidosis.org/facts/al/.* Accessed September 2021.

and 3–7 hour administration time required for IV daratumumab. The applicant further noted that given the cardiac and renal dysfunction which afflicts many AL amyloidosis patients and makes them poor candidates for large volume IV administration, rHuP20 is a critical component of DARZALEX FASPRO®. Per the applicant, daratumamab binds to the CD38 protein on the surface of the malignant plasma cells which are responsible for abnormal amyloid protein production in AL amyloidosis, directly killing the malignant CD38+ plasma cells and/or directing the immune system to destroy them. The immunomodulatory response consists of CD8+ clonal expansion, CD38 enzymatic inhibition, complement activation and cell recruitment to enable antibody dependent cellular phagocytosis (ADPC) and antibody dependent cellular cytotoxicity (ADCC). Per the applicant, the mechanism of actions of daratumumab in AL amyloidosis are the same as the mechanisms of action of daratumumab in multiple myeloma, since both disease entities are disorders of malignant CD38+ plasma cells.[68] [69] [70]

The applicant stated that without hyaluronidase, it is not possible to inject more than 2–3 mL of drug directly into the subcutaneous tissue under the skin. Per the applicant rHuPH20 naturally mimics natural hyaluronidase and increases the permeability of subcutaneous tissue by degrading hyaluronan. By co-formulating daratumumab with rHuPH20, it becomes possible for 15 mL containing 1,800 mg of daratumamab to be administered subcutaneously in approximately 3 to 5 minutes. The applicant stated that the ability to administer daratumumab subcutaneously reduces the reaction rate to daratumumab, may improve convenience and patient satisfaction, and greatly reduces the volume of administration, which is critical in light of the cardiac dysfunction and kidney dysfunction which afflict many patients with AL amyloidosis.

With respect to the newness criterion, the applicant stated that DARZALEX FASPRO® was granted accelerated approval from FDA on January 15, 2021, indicated for the treatment of adult patients with light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. Per the applicant, DARZALEX FASPRO® is not indicated and recommended for the treatment of patients with AL amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.[71] The applicant also stated that DARZALEX FASPRO® received FDA approval on September 26, 2019, for the treatment of adult patients with multiple myeloma as part of a combination therapy in newly diagnosed patients eligible for autologous stem cell transplant, and on May 1, 2020, for the treatment of patients with multiple myeloma. As stated previously, the indication for which the applicant submitted an application for new technology add-on payments is for the treatment of adult patients with AL amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. The applicant stated that DARZALEX FASPRO® for newly diagnosed AL amyloidosis was commercially available immediately following the accelerated approval granted by FDA. The recommended dosage for DARZALEX FASPRO® for newly diagnosed AL amyloidosis is 1,800 mg of daratumumab and 30,000 units of hyaluronidase administered subcutaneously over approximately 3 to 5 minutes in combination with bortezomib, cyclophosphamide and dexamethasone. According to the applicant, patients receiving DARZALEX FASPRO® for this indication receive a weekly dose for the first 8 weeks (week 1 to week 8), one dose every 2 weeks from week 9 to week 24, followed by one dose monthly from week 25 onward until disease progression for a maximum of 2 years.

The applicant submitted a request for a unique ICD–10–PCS code to identify procedures involving the administration of DARZALEX FASPRO®, and was granted approval to identify DARZALEX FASPRO® administration with ICD–10–PCS code XW01318 (Introduction of daratumumab and hyaluronidase-fihj into subcutaneous tissue, percutaneous approach, new technology group 8), effective October 1, 2022. We note that DARZALEX FASPRO® is also approved for multiple indications for the treatment of patients with multiple myeloma, and this PCS code would not uniquely identify use of the technology for the indication for which the applicant has applied for a new technology add-on payment. The applicant stated that E85.81 (Light chain (AL) amyloidosis) may be used to currently identify the indication for DARZALEX FASPRO® under the ICD–10–CM coding system. Therefore, the administration of DARZALEX FASPRO® for the AL amyloidosis indication could be uniquely identified with XW01318, in combination with E85.81.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

With respect to the first criterion, whether a technology uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that it does not use the same or similar mechanism of action as existing technologies. The applicant stated that DARZALEX FASPRO® was the first drug approved by FDA for treatment of AL amyloidosis and its mechanism of action is different from that of any other drug previously used to treat AL amyloidosis. According to the applicant, the other therapies currently used to treat amyloidosis off-label (for example, bortezomib, cyclophosphamide, melphalan, lenlidomide) all have different mechanisms of action; none of them are monoclonal antibodies that specifically bind to CD38 on malignant plasma cells. The applicant stated that bortezomib induces cell death of the malignant plasma cell by inhibition of the 26S proteasome which plays a key role in cell survival by regulating protein breakdown in a controlled fashion. The applicant further stated that when bortezomib inhibits proteasome function, the normal balance within a cell is disrupted, resulting in a buildup of cell cycle and regulatory proteins which eventually leads to cell death.[72] [73] Per the applicant, lenalidomide is an immunomodulator which modulates the E3 ubiquitin ligase complex. Modulation of this E3 ubiquitin ligase

[68] de Weers et al. Daratumumab, a Novel Therapeutic Human CD38 Monoclonal Antibody, Induces Killing of Multiple Myeloma and Other Hematogical Tumors. J Immunol 2011;186:1840–1848).

[69] Overdijk et al. Antibody-mediated phagocytosis contributes to the anti-tumor activity of the therapeutic antibody daratumumab in lymphoma and multiple myeloma. MAbs.2015;7:311–321).

[70] Krejcik J, Casneuf T, Nijhof IS, et al. Daratumumab depletes CD38+ immune regulatory cells, promotes T-cell expansion, and skews T-cell repertoire in multiple myeloma. Blood 2016; 128: 384–94.

[71] According to the applicant, continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

[72] Adams et al. Proteasome Inhibitors: A Novel Class of Potent and Effective Antitumor Agents. Cancer Res 1999;55; 2615–2622.

[73] Adams et al. The proteasome: a suitable antineoplastic target. Nat Rev Cancer 2004; 4:349–360.

complex by lenalidomide eventually leads to enhanced function of specific immune cells and induction of cell death and the exact mechanism of action of lenalidomide is still not fully understood.[74] [75] The applicant stated that both melphalan and cyclophosphamide are alkylating chemotherapy drugs that add an alkyl group to the guanine base of the DNA molecule, preventing the strands of the double helix from linking, which causes breakage of the DNA strands, affecting the ability of the cancer cell to multiply. Per the applicant, like bortezomib and lenalidomide, melphalan and cyclophosphamide are not approved by FDA for the use in patients with AL amyloidosis. The applicant also noted that while the National Comprehensive Cancer Network® (NCCN®) Guidelines for Systemic Light Chain Amyloidosis state that both IV and SQ daratumumab can be used to treat previously treated amyloidosis,[76] IV daratumumab is not approved by FDA for the treatment of patients with amyloidosis (newly diagnosed and previously treated). The applicant also stated that DARZALEX FASPRO® is the more appropriate option in the AL amyloidosis patient population due to the fact that subcutaneous dosing has a negligible volume administration (15 ml for SC vs up to 1,000 ml for IV), which is particularly important in patients with AL amyloidosis who often have compromised cardiac and renal function due to the amyloid deposition in cardiac and kidney tissue.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that this product is not expected to change the DRG assignment of a case when used for the treatment of AL amyloidosis.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that DARZALEX FASPRO® does not meet this criterion because it was the first approved drug to treat patients with AL amyloidosis. The applicant also stated that the NCCN® Guidelines for Systemic Light Chain Amyloidosis reflect the limited treatment options for this specific disease. The applicant further stated that DARZALEX FASPRO® in combination with CyBorD is the only treatment with a Category 1 recommendation [77] in the NCCN® Guidelines for patients with newly diagnosed AL amyloidosis.[78]

In summary, the applicant believes that DARZALEX FASPRO® is not substantially similar to other currently available therapies and/or technologies because it has a unique mechanism of action and because it is the first FDA approved treatment for AL amyloidosis.

We invited public comments on whether DARZALEX FASPRO® is substantially similar to existing technologies and whether DARZALEX FASPRO® meets the newness criterion.

Comment: The applicant submitted a comment reiterating its belief that DARZALEX FASPRO® meets the newness criterion because it was the first drug approved by FDA for patients with newly diagnosed light chain amyloidosis and that the mechanism of action is different from that of any other drug previously used to treat AL amyloidosis in that it is a monoclonal antibody that specifically binds to CD38 on malignant cancer cells. The applicant stated that because of this unique mechanism of action, DARZALEX FASPRO® for AL is not substantially similar to current treatments for AL and therefore meets the newness criterion.

Response: We thank the applicant for its comment. Based on our review of comments received and information submitted by the applicant as part of its FY 2023 new technology add-on payment application for DARZALEX FASPRO®, we agree with the applicant that DARZALEX FASPRO® has a unique mechanism of action as the first FDA approved treatment for AL amyloidosis. Therefore, we believe that DARZALEX FASPRO® is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence when DARZALEX FASPRO® was approved by FDA for the treatment of adult patients with light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients, on January 15, 2021.

With respect to the cost criterion, the applicant presented the following analysis to demonstrate that DARZALEX FASPRO® meets the cost criterion. To identify cases representing patients who may be eligible for treatment with DARZALEX FASPRO®, the applicant searched the FY 2019 MedPAR database released with the FY 2022 IPPS final rule and stated that it used fee-for-service IPPS discharges, plus Maryland hospital discharges. The applicant searched for claims reporting ICD–10–CM diagnosis code E85.81 (Light chain amyloidosis) in conjunction with at least one of the following additional ICD–10–CM diagnosis codes:

BILLING CODE 4120–01–P

[74] Kastritis et al. Primary treatment of light chain amyloidosis with Bortezomib, lenalidomide and dexamethasone. Blood Adv 2019;3:3002–3009.

[75] Revlimid Prescribing Info.

[76] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Systemic Light Chain amyloidosis (Version 1.2022). National Comprehensive Cancer Network. *www.nccn.org.* Published August 29 June 2021. Accessed July 21, 2021.

[77] Per the NCCN®, a Category 1 recommendation is ''Based upon high-level evidence, there is uniform NCCN® consensus that the intervention is appropriate.''

[78] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Systemic Light Chain amyloidosis (Version 1.2022). National Comprehensive Cancer Network. *www.nccn.org.* Published August 29 June 2021. Accessed July 21, 2021.

ICD-10-CM	DESCRIPTION
C90.00	Multiple myeloma not having achieved remission
D63.1	Anemia in chronic kidney disease
E85.4	Organ-limited amyloidosis
G62.9	Polyneuropathy, unspecified
I11.0	Hypertensive heart disease with heart failure
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I43	Cardiomyopathy in diseases classified elsewhere
I48.0	Paroxysmal atrial fibrillation
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I95.1	Orthostatic hypotension
I95.9	Hypotension, unspecified
N17.9	Acute kidney failure, unspecified
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.6	End stage renal disease
Z99.2	Dependence on renal dialysis

The applicant excluded cases with a length of stay greater than 7 days from the analysis. According to the applicant, administration of DARZALEX FASPRO® would likely be delayed if a patient becomes seriously ill during the course of treatment, so it is unlikely a patient would receive DARZALEX FASPRO® during an inpatient stay lasting longer than 7 days. The applicant indicated that based on the advice of clinical experts, it also excluded cases mapped to the following MS–DRGs, as DARZALEX FASPRO® would not be an appropriate treatment for patients receiving treatment for such conditions:

MS-DRG	DESCRIPTION
003	ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis except Face, Mouth and Neck with Major O.R. Procedures
016	Autologous Bone Marrow Transplant with CC/MCC
024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
026	Craniotomy and Endovascular Intracranial Procedures with CC
064	Intracranial Hemorrhage or Cerebral Infarction with MCC
065	Intracranial Hemorrhage or Cerebral Infarction with CC OR TPA in 24 Hours
070	Nonspecific Cerebrovascular Disorders with MCC
094	Bacterial and Tuberculous Infections of Nervous System with MCC
098	Non-Bacterial Infection of Nervous System except Viral Meningitis with CC
152	Otitis Media and URI with MCC
153	Otitis Media and URI without MCC
163	Major Chest Procedures with MCC
164	Major Chest Procedures with CC
175	Pulmonary Embolism with MCC or Acute Cor Pulmonale
176	Pulmonary Embolism without MCC
177	Respiratory Infections and Inflammations with MCC
178	Respiratory Infections and Inflammations with CC
180	Respiratory Neoplasms with MCC
189	Pulmonary Edema and Respiratory Failure
193	Simple Pneumonia and Pleurisy with MCC
194	Simple Pneumonia and Pleurisy with CC
207	Respiratory System Diagnosis with Ventilator Support >96 Hours
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC
267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC
270	Other Major Cardiovascular Procedures with MCC
271	Other Major Cardiovascular Procedures with CC
280	Acute Myocardial Infarction, Discharged Alive with MCC
281	Acute Myocardial Infarction, Discharged Alive with CC
283	Acute Myocardial Infarction, Expired with MCC
296	Cardiac Arrest, Unexplained with MCC
330	Major Small and Large Bowel Procedures with CC

371	Major Gastrointestinal Disorders and Peritoneal Infections with MCC
372	Major Gastrointestinal Disorders and Peritoneal Infections with CC
377	Gastrointestinal Hemorrhage with MCC
378	Gastrointestinal Hemorrhage with CC
386	Inflammatory Bowel Disease with CC
388	Gastrointestinal Obstruction with MCC
389	Gastrointestinal Obstruction with CC
417	Laparoscopic Cholecystectomy without C.D.E. with MCC
418	Laparoscopic Cholecystectomy without C.D.E. with CC
436	Malignancy of Hepatobiliary System or Pancreas with CC
454	Combined Anterior and Posterior Spinal Fusion with CC
469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
481	Hip Femur Procedures except Major Joint with CC
483	Major Joint or Limb Reattachment Procedures of Upper Extremities
521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
535	Fractures of Hip and Pelvis with MCC
536	Fractures of Hip and Pelvis without MCC
602	Cellulitis with MCC
603	Cellulitis without MCC
652	Kidney Transplant
666	Prostatectomy with CC
742	Uterine and Adnexa Procedures for Non-Malignancy with CC/MCC
813	Coagulation Disorders
820	Lymphoma and Leukemia with Major O.R. Procedures with MCC
823	Lymphoma and Non-Acute Leukemia with Other Procedures with MCC
824	Lymphoma and Non-Acute Leukemia with Other Procedures with CC
834	Acute Leukemia without Major O.R. Procedures with MCC
835	Acute Leukemia without Major O.R. Procedures with CC
837	Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC
840	Lymphoma and Non-Acute Leukemia with MCC
841	Lymphoma and Non-Acute Leukemia with CC
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC
854	Infectious and Parasitic Diseases with O.R. Procedures with CC
856	Postoperative or Post-Traumatic Infections with O.R. Procedures with MCC
864	Fever and Inflammatory Conditions
867	Other Infectious and Parasitic Diseases Diagnoses with MCC
868	Other Infectious and Parasitic Diseases Diagnoses with CC
870	Septicemia or Severe Sepsis with MV >96 HOURS
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC
872	Septicemia or Severe Sepsis without MV >96 Hours without MCC
918	Poisoning and Toxic Effects of Drugs without MCC
919	Complications of Treatment with MCC
920	Complications of Treatment with CC
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
982	Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC

After applying the case selection and exclusion criteria, the applicant's search resulted in the identification of 114 MS–DRGs using the FY 2019 MedPAR file dataset. The applicant imputed a case count of 11 for 104 MS–DRGs with

fewer than 11 cases, resulting in a total of 1,494 cases mapping to the 114 MS–DRGs.

MS-DRG	Title	% of Cases
291	Heart Failure and Shock with MCC	7.23%
545	Connective Tissue Disorders with MCC	4.22%
683	Renal Failure with CC	2.14%
546	Connective Tissue Disorders with CC	2.01%
292	Heart Failure and Shock with CC	1.81%
312	Syncope and Collapse	1.47%
286	Circulatory Disorders except AMI, with Cardiac Catheterization with MCC	1.27%
640	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes with MCC	1.20%
682	Renal Failure with MCC	1.14%
308	Cardiac Arrhythmia and Conduction Disorders with MCC	0.94%
391	Esophagitis, Gastroenteritis and Miscellaneous Digestive Disorders with MCC	0.74%
314	Other Circulatory System Diagnoses with MCC	0.74%
674	Other Kidney and Urinary Tract Procedures with CC	0.74%
641	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes without MCC	0.74%
190	Chronic Obstructive Pulmonary Disease with MCC	0.74%
313	Chest Pain	0.74%
392	Esophagitis, Gastroenteritis and Miscellaneous Digestive Disorders without MCC	0.74%
393	Other Digestive System Diagnoses with MCC	0.74%
699	Other Kidney and Urinary Tract Diagnoses with CC	0.74%
309	Cardiac Arrhythmia and Conduction Disorders with CC	0.74%
689	Kidney and Urinary Tract Infections with MCC	0.74%
698	Other Kidney and Urinary Tract Diagnoses with MCC	0.74%
811	Red Blood Cell Disorders with MCC	0.74%
274	Percutaneous and Other Intracardiac Procedures without MCC	0.74%
304	Hypertension with MCC	0.74%
660	Kidney and Ureter Procedures for Non-Neoplasm with CC	0.74%
673	Other Kidney and Urinary Tract Procedures with MCC	0.74%
808	Major Hematological and Immunological Diagnoses except Sickle Cell Crisis and Coagulation Disorders with MCC	0.74%
847	Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC	0.74%
948	Signs and Symptoms without MCC	0.74%
187	Pleural Effusion with CC	0.74%
242	Permanent Cardiac Pacemaker Implant with MCC	0.74%
264	Other Circulatory System O.R. Procedures	0.74%
287	Circulatory Disorders except AMI, with Cardiac Catheterization without MCC	0.74%
522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC	0.74%
690	Kidney and Urinary Tract Infections without MCC	0.74%
812	Red Blood Cell Disorders without MCC	0.74%
988	Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC	0.74%
071	Nonspecific Cerebrovascular Disorders with CC	0.74%
186	Pleural Effusion with MCC	0.74%
226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC	0.74%
227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC	0.74%
243	Permanent Cardiac Pacemaker Implant with CC	0.74%
246	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents	0.74%

300	Peripheral Vascular Disorders with CC	0.74%
394	Other Digestive System Diagnoses with CC	0.74%
432	Cirrhosis and Alcoholic Hepatitis with MCC	0.74%
441	Disorders of the Liver except Malignancy, Cirrhosis or Alcoholic Hepatitis with MCC	0.74%
477	Biopsies of Musculoskeletal System and Connective Tissue with MCC	0.74%
542	Pathological Fractures and Musculoskeletal and Connective Tissue Malignancy with MCC	0.74%
552	Medical Back Problems without MCC	0.74%
596	Major Skin Disorders without MCC	0.74%
809	Major Hematological and Immunological Diagnoses except Sickle Cell Crisis and Coagulation Disorders with CC	0.74%
947	Signs and Symptoms with MCC	0.74%
052	Spinal Disorders and Injuries with CC/MCC	0.74%
057	Degenerative Nervous System Disorders without MCC	0.74%
074	Cranial and Peripheral Nerve Disorders without MCC	0.74%
091	Other Disorders of Nervous System with MCC	0.74%
124	Other Disorders of the Eye with MCC	0.74%
149	Dysequilibrium	0.74%
155	Other Ear, Nose, Mouth and Throat Diagnoses with CC	0.74%
157	Dental and Oral Diseases with MCC	0.74%
166	Other Respiratory System O.R. Procedures with MCC	0.74%
191	Chronic Obstructive Pulmonary Disease with CC	0.74%
196	Interstitial Lung Disease with MCC	0.74%
205	Other Respiratory System Diagnoses with MCC	0.74%
206	Other Respiratory System Diagnoses without MCC	0.74%
225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI, HF or Shock without MCC	0.74%
247	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC	0.74%
250	Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC	0.74%
252	Other Vascular Procedures with MCC	0.74%
253	Other Vascular Procedures with CC	0.74%
260	Cardiac Pacemaker Revision except Device Replacement with MCC	0.74%
299	Peripheral Vascular Disorders with MCC	0.74%
303	Atherosclerosis without MCC	0.74%
305	Hypertension without MCC	0.74%
311	Angina Pectoris	0.74%
315	Other Circulatory System Diagnoses with CC	0.74%
326	Stomach, Esophageal and Duodenal Procedures with MCC	0.74%
350	Inguinal and Femoral Hernia Procedures with MCC	0.74%
368	Major Esophageal Disorders with MCC	0.74%
433	Cirrhosis and Alcoholic Hepatitis with CC	0.74%
445	Disorders of the Biliary Tract with CC	0.74%
464	Wound Debridement and Skin Graft except Hand or Musculoskeletal and Connective Tissue Disorders with CC	0.74%
478	Biopsies of Musculoskeletal System and Connective Tissue with CC	0.74%
480	Hip and Femur Procedures except Major Joint with MCC	0.74%
500	Soft Tissue Procedures with MCC	0.74%
513	Hand or Wrist Procedures, except Major Thumb or Joint Procedures with CC/MCC	0.74%
515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC	0.74%
516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC	0.74%
518	Back and Next Procedures except Spinal Fusion with MCC or Disc Device Or Neurostimulator	0.74%
537	Sprains, Strains, and Dislocations of Hip, Pelvis and Thigh with CC/MCC	0.74%
543	Pathological Fractures and Musculoskeletal and Connective Tissue Malignancy with CC	0.74%
547	Connective Tissue Disorders without CC/MCC	0.74%
551	Medical Back Problems with MCC	0.74%
553	Bone Diseases and Arthropathies with MCC	0.74%
554	Bone Diseases and Arthropathies without MCC	0.74%
555	Signs and Symptoms of Musculoskeletal System and Connective Tissue with MCC	0.74%

559	Aftercare, Musculoskeletal System and Connective Tissue with MCC	0.74%
604	Trauma to the Skin, Subcutaneous Tissue and Breast with MCC	0.74%
638	Diabetes with CC	0.74%
643	Endocrine Disorders with MCC	0.74%
644	Endocrine Disorders with CC	0.74%
694	Urinary Stones without MCC	0.74%
696	Kidney and Urinary Tract Signs and Symptoms without MCC	0.74%
846	Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC	0.74%
866	Viral Illness without MCC	0.74%
876	O.R. Procedures with Principal Diagnosis of Mental Illness	0.74%
880	Acute Adjustment Reaction and Psychosocial Dysfunction	0.74%
884	Organic Disturbances and Intellectual Disability	0.74%
907	Other O.R. Procedures for Injuries with MCC	0.74%
908	Other O.R. Procedures for Injuries with CC	0.74%
949	Aftercare with CC/MCC	0.74%
987	Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC	0.74%

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The applicant determined an average unstandardized case weighted charge per case of $47,599.

The applicant did not remove charges for related or prior technologies because, per the applicant, DARZALEX FASPRO® would not replace other therapies a patient may receive during an inpatient stay. Next, the applicant standardized the charges using the FY 2022 IPPS/LTCH PPS final rule impact file and applied a 4-year inflation factor of 1.281834 or 28.1834% based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule to update the outlier threshold (86 FR 45542). The applicant then added charges for the new technology by multiplying the per treatment cost of DARZALEX FASPRO® by the inverse of the national average drug CCR of 0.187 from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966).

The applicant calculated a final inflated average case-weighted standardized charge per case of $92,916, which exceeded the average case-weighted threshold amount of $61,426. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that DARZALEX FASPRO® meets the cost criterion.

We invited public comment on whether DARZALEX FASPRO® meets the cost criterion.

Comment: The applicant submitted a comment reiterating its belief that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, DARZALEX FASPRO® meets the cost criterion.

Response: We thank the commenter for its comment. We agree the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, DARZALEX FASPRO® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that DARZALEX FASPRO® represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The applicant also asserted that DARZALEX FASPRO® demonstrates significant improvement in a number of clinical outcomes including hematologic complete response (hemCR), prolonged survival free from major organ deterioration, increased cardiac and renal response rates, with a demonstrated safety and tolerability profile and no negative impact to health-related quality of life based on patient-reported outcomes.

With regard to the claim that DARZALEX FASPRO® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, the applicant stated that the initial standard of therapy (CyBorD) is considered inadequate, as most patients do not respond adequately to the CyBorD regimen alone. Furthermore, according to the applicant, the ANDROMEDA data shows that >80% of patients do not achieve a hemCR, >75% of patients with cardiac disease do not have an organ response, and >75% of patients with renal disease do not have an organ response when treated with the initial standard of therapy CyBorD. Per the applicant, there is a high unmet need to improve treatment for AL amyloidosis patients. The applicant stated that rapid and deep response like hemCR are critical and are strongly associated with organ response and improved survival in AL amyloidosis.[79] Per the applicant, adding DARZALEX FASPRO® to CyBorD increases the hemCR rate by three-fold and doubles the cardiac and renal response rates, thereby addressing this high unmet medical need.

With regard to the claim that the use of DARZALEX FASPRO® significantly improves clinical outcomes for a patient population as compared to currently available treatments, as stated previously, the applicant asserted that DARZALEX FASPRO® represents a substantial clinical improvement over existing technologies because it: (1) demonstrates a consistent safety profile; (2) significantly improves hematologic complete response (hemCR rates); (3) maintains the increased hemCR rates for pre-specified subgroups; (4) shortens the time to hemCR; (5) improves very good partial response (VGPR) or better rates; (6) substantially improves cardiac response at 6 and at 12 months; (7) improves renal response at 6 and at 12 months; (8) improves major-organ deterioration or progression-free survival (MOD–PFS); (9) improves Global Health status and fatigue as of cycle 6 of treatment, and maintains health-related quality of life (HRQoL); and (10) provides important advantages for the population with AL.

In support of these claims, the applicant submitted the ANDROMEDA phase 3 trial as well as presentations related to these trials. The applicant stated that data in the ANDROMEDA study demonstrated that DARZALEX FASPRO® led to significantly better outcomes both at the time of the

[79] Comenzo RL, Reece D, Palladini G, et al. Consensus guidelines for the conduct and reporting of clinical trials in systemic light chain amyloidosis. Leukemia. 2012;26: 2317–2325.

primary analysis [80] as well as at the time of updated analyses which were presented at the 2021 ASCO annual meeting and 2021 EHA annual meeting.[81]

ANDROMEDA was a randomized, open-label, phase 3 study of 388 patients with newly diagnosed AL amyloidosis randomized 1:1 to receive 6 cycles of CyBorD, either alone (control group, n=193) or in combination with daratumumab SC (that is, DARZALEX FASPRO®), followed by DARZALEX FASPRO® monotherapy every 4 weeks for up to 24 additional cycles (daratumumab group, n=195). The study enrolled patients between May 3, 2018 and August 15, 2019. Median age was 64 (range 34–87). The study reported a median 11.4 month follow-up for the published trial, and 20.3 months for the follow-up data. The primary endpoint was hemCR, defined as having negative serum and urine immunofixation and a free light chain ratio (FLCr) within the reference range or abnormal free light-chain ratio if the uninvolved free light chain (uFLC) is higher than the involved free light chain (iFLC). According to the applicant, this definition of hemCR is in line with a recent clarification of the Internal Society of Amyloidosis guidelines.[82] Secondary endpoints were survival free from major organ deterioration or hematologic progression (composite end point that included end-stage cardiac or renal failure, hematologic progression), or death, organ response, overall survival, hematologic complete response at 6 months, VGPR or better, time to and duration of hematologic complete response, time to next treatment, and reduction in fatigue. The applicant noted that the safety population in the ANDROMEDA study consisted of 193 patients in the daratumumab arm and 188 patients in the control arm.

The applicant also cited an oral presentation, presented at the American Society of Clinical Oncology (ASCO) 2021 and European Hematology Association (EHA) 2021 annual meetings, with updated data from the ANDROMEDA study after 20.3 months of follow-up, which described sustained primary outcome of higher rates of hemCR across subgroups as well as improved secondary endpoints of cardiac and renal response rate at 12 months. In the intent to treat population, there were 11 deaths in the CyBorD group compared to 7 deaths in the control group.[83]

In support of its assertion that DARZALEX FASPRO® demonstrates a consistent safety profile, the applicant cited Kastritis et al., discussed previously, stating that the safety profiles of daratumumab and bortezomib, cyclophosphamide, and dexamethasone in the ANDROMEDA trial were consistent with their known profiles and the underlying disease from previous trials.[84] To support its assertion that DARZALEX FASPRO® significantly improves hemCR rate, the applicant stated that the trial results showed that patients treated with DARZALEX FASPRO® demonstrated a statistically significant increase in hemCR compared to control (53.3% versus 18.1%; relative risk ratio, 2.9; 95% CI, 2.1 to 4.1; odds ratio, 5.1; 95% CI, 3.2 to 8.2; p <0.001 for both comparisons) at the 11.4 month median follow-up. To support its assertion that DARZALEX FASPRO® results in a shorter time to hemCR, the applicant noted that in the trial, median time to hemCR was 60 days in the daratumumab group and 85 days in the control group. In support of its assertion that the increased hemCR rate was maintained for pre-specified subgroups, the applicant also stated that hemCR remained consistent in most prespecified subgroups (for example, sex, age, weight, race, cardiac stage, etc.) receiving daratumumab.[85] The applicant also cited results from the oral presentation, discussed previously, stating that after a median follow up of 20.3 months, the percentage of patients who achieved hemCR increased to 59% in the daratumumab group vs 19% in the control group (odds ratio: 5.9; 95% CI, 3.7 to 9.4; P <0.001), and that this advantage was seen consistently across all prespecified subgroups.[86] The applicant stated that rapid and deep hematologic responses are critical and are strongly associated with organ response and improved survival in AL amyloidosis.[87]

In support of its assertion that DARZALEX FASPRO® improved VGPR or better rates, the applicant also stated that the trial demonstrated that the secondary endpoint of VGPR or better was 78.5% in the daratumumab group and 49.2% in the control group (relative risk ratio, 1.6; 95% CI, 1.4 to 1.9; odds ratio, 3.8; 95% CI, 2.4 to 5.9).[88] Per the applicant, the substantial improvements in hematologic response rates and other endpoints like cardiac and renal response and MOD–PFS indicate the clinical meaningfulness of these efficacy results.

In support of its assertion that DARZALEX FASPRO® substantially improves cardiac response at 6 and at 12 months, according to the applicant, of the subgroup that was evaluated for cardiac response (118 in the daratumumab group and 117 in the control group), 41.5% in the daratumumab group and 22.2% in the control group (odds ratio, 2.44; 95% CI: 1.35 to 4.42) demonstrated a cardiac response at 6 months.[89] The applicant noted that at a median follow up of 20.3 months, cardiac response rates were higher with in the daratumumab group compared to CyBorD alone at 6 months (42% versus 22%, odds ratio 2.4, 95% CI 1.4 to 4.4; P = .0029) and at 12 months (57% versus 28%, odds ratio 3.5 95% CI 2.0 to 6.2; P <0.0001).[90] In addition, in support of its assertion that

[80] Kastritis et al. Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis. New England Journal of Medicine (NEJM). 2021; 385:46–58.

[81] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[82] Palladini et al. Daratumumab plus CyBord for patients with newly diagnosed AL amyloidosis: safety run-in results of ANDROMEDA. Blood.2020;136:71–80.

[83] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[84] Kastritis E, et al., Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis, N Eng J Med. 2021; 385:46–58.

[85] Kastritis E, et al., Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis, N Eng J Med. 2021; 385:46–58.

[86] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[87] Comenzo RL, Reece D, Palladini G, et al. Consensus guidelines for the conduct and reporting of clinical trials in systemic light chain amyloidosis. Leukemia. 2012;26: 2317–2325.

[88] Kastritis et al., Daratumumab for immunoglobulin light-chain amyloidosis. N Eng J Med 2021; 385:48–58.

[89] Kastritis E, et al., Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis, N Eng J Med. 2021; 385:46–58.

[90] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

DARZALEX FASPRO® improves renal response at 6 and at 12 months, the applicant noted that in the subgroup evaluated for renal response (117 in the daratumumab group and 113 in the control group), 53.0% of patients in the daratumumab group and 23.9% in the control group (odds ratio, 3.34; 95% CI: 1.88 to 5.94) demonstrated a renal response at 6 months.[91] The applicant noted that at a median follow up of 20.3 months, renal response rates were higher with in the daratumumab group compared to CyBorD alone at 6 months (54% vs 27%; odds ratio 3.3 95% CI 1.9 to 5.9; P <0.0001) and at 12 months (57% vs 27%; odds ratio 4.1 95% CI 2.3 to 7.3; P <0.0001).[92] The applicant noted that the percentages of patients who had a cardiac or renal response were substantially higher in the daratumumab group than in the control group, which it stated was an important finding given that organ responses are also a predictor of improved survival.

In support of its assertion that DARZALEX FASPRO® improves MOD–PFS, the applicant noted significant findings of secondary endpoint survival free from major organ deterioration or hematologic progression in the daratumumab group compared to control (hazard ratio for major organ deterioration, hematologic progression, or death, 0.58; 95% CI, 0.36 to 0.93; P = 0.02).[93]

With regard to the claim that DARZALEX FASPRO® improves Global Health status (GHS) and fatigue as of cycle 6 of treatment, as well as maintains HRQoL, the applicant cited a poster presentation of a subgroup analysis on patient reported outcomes (PRO) for patients participating in the ANDROMEDA study.[94] The applicant noted that the patients were provided with PRO questionnaires and assessed on day 1 of cycles −1–6 as well as every 8 weeks thereafter in the daratumumab group. The applicant stated that of the 388 patients randomized in the study, compliance rates for all PRO questionnaires were >90% at baseline and >83% through Cycle 6. The questionnaires included the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30-item (EORTC QLQ–C30), the EuroQol 5-dimensional descriptive system (EQ–5D–5L), and Short Form-36 (SF–36). Secondary endpoints centered around improvements in EORTC QLQ–C30 global health status (GHS), fatigue scale scores, and SF–36 mental component summary (MCS) score. Exploratory outcomes included physical function assessment, symptom improvement, functional improvement, and health utility as measured by the SF–36, EORTC QLQC30 with supplemental symptom items, and the EQ–5D–5L.

The applicant stated that the results from this presentation show that following Cycle 6, improvements in GHS and fatigue were reported in patients in the treatment group, and that these findings further support the value of daratumumab SQ plus CyBorD (Dara-CyBorD) in patients with AL amyloidosis. The applicant also stated that patients with AL amyloidosis treated with Dara-CyBorD experienced clinical improvements without any decrement in HRQoL over 6 cycles. The applicant noted that the findings demonstrated that the median time to improvement was shorter in the treatment group than in the control group for EORTC QLQ–C30 GHS (CyBorD: 16.79 months, 95% CI:11.79 to NE, Dara-CyBorD: 7.82 months, 95% CI: 3.94 to 17.58, HR 1.53; 95% CI: 1.10 to 2.13), fatigue scales (CyBorD: NE, 95% CI:8.44 to NE, Dara-CyBorD: 9.30 months, 95% CI: 5.55 to 13.01, HR 1.39; 95% CI: 1.00 to 1.93) and EQ–5D–5L visual analog scale (CyBorD: NE, 95% CI:16.79 to NE, Dara-CyBorD: 10.05 months, 95% CI: 8.41 to NE, HR 1.21; 95% CI: 0.86 to 1.71). The applicant also noted that the findings demonstrated that median time to worsening was longer in the treatment group than in the control group for EORTC QLQ–C30 GHS (CyBorD: 2.89 months, 95% CI:2.23 to 3.78, Dara-CyBorD: 4.70 months, 95% CI: 2.83 to 7.36, HR 0.87; 95% CI: 0.66 to 1.13) and fatigue scales (CyBorD: 3.75 months, 95% CI: 2.86 to 4.76 Dara-CyBorD: 8.84 months, 95% CI: 3.75 to NE, HR 0.78; 95% CI: 0.58 to 1.04) and EQ–5D–5L visual analog scale (CyBorD: 3.38 months, 95% CI:2.79 to 4.67, Dara-CyBorD: 4.14 months, 95% CI: 2.86 to 7.66, HR 0.89; 95% CI: 0.67 to 1.19).[95]

Finally, the applicant stated that DARZALEX FASPRO® provides important advantages to the population with AL amyloidosis because the subcutaneous administration allows for a negligible volume of administration and a reduced rate of systemic administration-related reactions.[96]

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28234 through 28235), after review of the information provided by the applicant, we stated we had the following concerns regarding whether DARZALEX FASPRO® meets the substantial clinical improvement criterion. First, with respect to the ANDROMEDA trial, we noted that the study's open label and unblinded design adds a potential risk of bias which may affect the treatment effect reported by the applicant. Additionally, we noted that the ANDROMEDA trial used stratified randomization which resulted in potentially substantive differences between the treatment and control group at baseline; for example, the control group was slightly older, with more males, and more people at higher cardiac stage (based on N-terminal pro-B-type natriuretic peptide and high-sensitivity cardiac troponin T). The groups also differed by Eastern Cooperative Oncology Group (ECOG) performance-status scores and uninvolved free light chain (dFLC) levels, and renal function. Additionally, compared to control, the daratumumab group appeared to have higher rates of peripheral sensory neuropathy, upper respiratory infection, and neutropenia in the longer term data.[97] We questioned whether these differences noted at baseline are in fact significant and would have the potential to impact the treatment effect seen in this study. In terms of study outcomes, the ANDROMEDA study relied on hematologic and organ-based laboratory-based outcomes, but we questioned

[91] Kastritis E, et al., Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis, N Eng J Med. 2021; 385:46–58.

[92] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[93] Kastritis et al. Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis. NEJM. 2021;385:46–58.

[94] Sanchorawala et al., Health-Related Quality of Life in Patients with AL Amyloidosis Treated with Daratumumab, Bortezomib, Cyclophosphamide, and Dexamethasone: Results from the Phase 3 ANDROMEDA Study, Poster presentation at: American Society of Hematology (ASH) Annual Virtual Meeting; December 5–8, 2020.

[95] Sanchorawala et al., Health-Related Quality of Life in Patients with AL Amyloidosis Treated with Daratumumab, Bortezomib, Cyclophosphamide, and Dexamethasone: Results from the Phase 3 ANDROMEDA Study, Poster presentation at: American Society of Hematology (ASH) Annual Virtual Meeting; December 5–8, 2020.

[96] Kastritis et al. Daratumumab-Based Treatment for Immunoglobulin Light-Chain Amyloidosis. NEJM. 2021;385:46–58.

[97] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

whether a primary endpoint of overall survival would have provided stronger evidence.

Second, we had concerns about the generalizability of the ANDROMEDA population and subgroups. As clarified by the applicant during the New Technology Town Hall meeting, all subjects in the ANDROMEDA trial received DARZALEX FASPRO® in the outpatient setting. As such, we questioned whether the outcomes for this outpatient population are generalizable to patients who are sufficiently ill to require hospitalization. In regard to subpopulations, we noted that the prespecified groups and the studies of cardiac stage and Asian cohorts exhibit the same potential limitations of the main trial with small sample size, open-label, and limited follow-up. We noted that small sample size resulted in wider confidence intervals in some subgroups, which may limit the generalizability of the treatment results. For example, in the ANDROMEDA prespecified groups, the subgroups 'other' race, cardiac stage I at baseline, and renal stage III had wider confidence intervals than other subgroups. Finally, while the applicant provided a phase 2 poster presentation in support of DARZALEX FASPRO® we questioned the extent to which these results are generalizable to the indication for which the applicant has applied for the new technology add-on payment (that is, the treatment of adult patients with light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients) given that the indication within this source (that is monotherapy in patients with Stage 3B AL amyloidosis), does not match.[98]

We noted that the applicant provided the outcomes of secondary endpoints which appear to be exploratory or novel for some of the data presented in posters in support of its claims, such as the quality of life assessments [99] and hematologic response as measured by involved and uninvolved free light chain,[100] and we noted that some of the endpoints are still being studied and validated. Specifically, we questioned whether these surrogate endpoints may be used to appropriately evaluate the measure for which they are intended to assess. We requested further information on whether these secondary endpoints have been appropriately validated in relevant clinical settings.

We invited public comments on whether DARZALEX FASPRO® meets the substantial clinical improvement criterion.

Comment: The applicant submitted a comment in response to CMS' concerns pertaining to substantial clinical improvement. With respect to our concern that the open label and unblinded study design of the ANDROMEDA trial may result in a biased treatment effect, the applicant stated that clinical trials designed to evaluate treatment effects in patients with AL amyloidosis need to account for the heterogeneity of the disease, the number of affected organs, including the heart, kidney, and liver, and the severity of organ involvement. Per the applicant, in addition to randomization by chance to the experimental Dara-CyBorD arm or the control CyBorD arm, subjects in the ANDROMEDA trial were randomized by cardiac stage, by whether transplant was typically offered, and by renal function. The applicant stated that efficacy data were adjudicated by an independent review committee whose members were unaware of the trial-group assignments. The applicant stated that patients in the control arm were marginally older and that there were slightly more males than females but that these small differences are not expected to cause a major difference in outcomes. The applicant also stated that the slight increase in males in this study is similar to an analysis of U.S. commercial and Medicare Supplemental claims data that found the prevalence of AL amyloidosis is higher in males (approximately 55% male).[101]

The applicant stated that the percentage of subjects in cardiac stage IIIA was similar in the two treatment arms.[102] Per the applicant, neither the slightly higher percentage of subjects with cardiac stage IIIB (3.1% vs. 1.0%) in the CyBorD arm nor the observed small differences in the ECOG status and renal status between the two arms are expected to have a major difference on the final outcomes.

With regard to the concern regarding higher peripheral sensory neuropathy, upper respiratory infection, and neutropenia in longer term data for the daratumumab group compared to the control group, the applicant stated that the relative incidence of infections like pneumonia as well as peripheral sensory neuropathy and neutropenia should be interpreted in the context of longer treatment exposure for patients receiving Dara-CyBorD vs. CyBorD. The applicant stated that when adjusted for exposure to trial treatment, the incidence of overall and grade 3 or 4 adverse events was lower in the daratumumab group than in the control group.[103]

With regard to the concern regarding hematologic and organ-based laboratory-based outcomes instead of overall survival, the applicant stated that primary treatment is targeted toward suppression of amyloid light chain synthesis in order to improve organ function. The applicant stated that treatment efficacy is typically determined by hematologic response and that the current staging systems for AL amyloidosis are based on circulating markers of cardiac, renal, and B cell clonal disease and are used for clinical trial design and to determine patient management. The applicant stated that because clinical presentation and long-term outcomes depend on adequate organ function, complete response (CR) does not completely describe the clinical efficacy of treatment in patients with AL amyloidosis. The applicant stated that organ response rates can be used but there are limitations with only using these biomarkers to monitor organ response. The applicant stated that, in consultation with and with the approval of the FDA, major organ deterioration–progression free survival (MOD–PFS) and major organ deterioration–event free survival (MOD–EFS) were chosen as secondary endpoints and were calculated as a composite endpoint of clinically observable endpoints. The applicant stated that several clinical studies have demonstrated that hematologic and organ responses were

[98] Kastritis E, et al., Subcutaneous Daratumumab + Cyclophosphamide, Bortezomib, and Dexamethasone (CyBorD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 ANDROMEDA Study, Oral presentation at: American Society for Oncology (ASCO) Annual Virtual Meeting; June 4–8, 2021 & Oral presentation at: European Hematology Association (EHA) Annual Virtual Meeting; June 9–17, 2021.

[99] Sanchorawala et al., Health-Related Quality of Life in Patients with AL Amyloidosis Treated with Daratumumab, Bortezomib, Cyclophosphamide, and Dexamethasone: Results from the Phase 3 ANDROMEDA Study, Poster presentation at: American Society of Hematology (ASH) Annual Virtual Meeting; December 5–8, 2020.

[100] Comenzo et al., Reduction in Absolute Involved Free Light Chain and Difference Between Involved and Uninvolved Free Light Chain is Associated with Prolonged Major Organ Deterioration Progression Free survival in Patient with Newly Diagnosed AL Amyloidosis Receiving Bortezomib, Cyclophosphamide and Dexamethasone with or without Daratumumab: Results from ANDROMEDA, Oral presentation at: American Society of Hematology (ASH) Annual Virtual Meeting; December 5–8, 2020.

[101] Quock et al. Epidemiology of AL amyloidosis: a real-world study using US claims data. Blood Adv 2018: 2: 1046–1053.

[102] Kastritis et al., NEJM, 2021.

[103] Kastritis et al., NEJM, 2021.

very strong predictors of overall survival.[104] [105] [106]

With regard to the concern for generalizability of the study population in an outpatient setting, the applicant stated that many factors contribute to whether a patient is treated as an outpatient or as an inpatient. Per the applicant, patients with similar clinical status might be treated in the inpatient setting because of the availability of health care personnel, insurance status, and available outpatient resources for patient follow-up. The applicant stated that the ANDROMEDA study was performed in an outpatient setting but there were patients with cardiac organ involvement that might have been hospitalized for treatment of cardiac disease and may have also be receiving treatment for AL amyloidosis, either as initiation of treatment or a part of a subsequent treatment cycle. The applicant stated that although the number of inpatient hospitalized individuals receiving a treatment cycle with Dara-CyBorD is expected to be low, it is important to ensure health care equity and access to the only FDA approved drug for treatment of newly diagnosed AL amyloidosis, regardless of treatment setting.

With regard to the small sample size and large confidence intervals in subgroup studies, the applicant stated that the variability in subgroup sizes could lead to wide confidence intervals, especially in the smaller subgroup sizes. The applicant also stated that there is strong numerical trend for improved outcomes with similar odds ratios in the Dara-CyborD arm across all subgroups.

With regard to the concern that the poster presentation did not match the indication for which the applicant has applied for the new technology add-on payment, the applicant stated that the use of daratumumab monotherapy in cardiac stage IIIB is still under investigation and although related data might be included in supporting documents, this information should be considered investigational. The applicant stated that its request for the new technology add-on payment is limited to the FDA approved indication: treatment of adult patients with newly diagnosed AL amyloidosis with NYHA or Mayo cardiac stage IIIA or less in combination with CyBorD.

With regard to our inquiry about the use of exploratory secondary endpoints in relevant clinical settings, the applicant stated that information about patient reported outcomes assessing the impact of treatment on quality of life provides early positive findings associated with the addition of DARZALEX FASPRO® to the CyBorD treatment combination but agreed that the information is preliminary and additional patient reported outcomes need to be obtained for AL amyloidosis patients at the time of diagnosis, during follow-up, and as the disease progresses. The applicant stated that the exploratory endpoints of iFLC ≤20mg/L and dFLC ≤10 mg/L also confirm the consistency of improved results of adding daratumumab to CyBorD. Finally, the applicant stated that besides the exploratory endpoints, the ANDROMEDA trial used the established primary endpoint of hematologic CR and the secondary endpoint of organ response which are defined in the International Society of Amyloidosis (ISA) guidelines and have been shown to be very good predictors for overall survival.

We also received an additional comment stating that DARZALEX FASPRO® improves progression free survival and organ survival across staging and that its combination with CyBorD has become standard of care and frontline treatment for patients with AL amyloidosis. The commenter further stated that rapidly achieving normalization of circulating immunogloblin free light chain is critical to offer the best chances of organ response and survival as time is of the essence in this disease, and organ response cannot occur in the absence of a hematologic remission. The commenter stated that adequate reimbursement will allow healthcare providers to adequately serve this critically ill patient population in both inpatient and outpatient settings, and will prevent having to withhold or delay the best possible regimen in the face of a requirement for an inpatient stay.

Response: We thank the commenters for their comments regarding the substantial clinical improvement criterion. Based on the additional information received, we agree that DARZALEX FASPRO® represents a substantial clinical improvement over existing technologies for the treatment of AL amyloidosis patients because it demonstrates improved clinical outcomes as compared to the standard of care CyBorD, including a higher rate of hemCR and longer major MOD–PFS.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that DARZALEX FASPRO® meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2023. Cases involving the use of DARZALEX FASPRO® that are eligible for new technology add-on payments will be identified by ICD–10–PCS code XW01318 (Introduction of daratumumab and hyaluronidase-fihj into subcutaneous tissue, percutaneous approach, new technology group 8) in combination with ICD–10–CM code E85.81 (Light chain (AL) amyloidosis).

In its application, the applicant estimated that the cost of DARZALEX FASPRO® is $7,937.55 per patient. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of DARZALEX FASPRO® is $5,159.41 for FY 2023.

c. Hemolung Respiratory Assist System (Hemolung RAS)

ALung Technologies, Inc. submitted an application for new technology add-on payments for the Hemolung Respiratory Assist System (Hemolung RAS) for FY 2023. The applicant stated that the Hemolung RAS is the first and only FDA authorized technology for the treatment of acute, hypercapnic respiratory failure using an extracorporeal circuit to remove CO_2 directly from the blood. Per the applicant, patients experiencing acute, hypercapnic respiratory failure are unable to remove excess CO_2 waste molecules from their blood via their lungs, resulting in accumulation of CO_2 in their blood (hypercapnia), acid/base derangement (respiratory acidosis), and life-threatening clinical sequelae.[107] The applicant stated that the Hemolung RAS does not treat a specific disease but removes CO_2 directly from the blood to treat a variety of underlying respiratory disease states, including, but not limited to, cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD), and asthma, where CO_2 retention (hypercapnia) is the primary cause of continued clinical deterioration.

Per the applicant, the Hemolung RAS provides low-flow, veno-venous extracorporeal carbon dioxide removal ($ECCO_2R$) using a 15.5 French dual lumen catheter inserted percutaneously in the femoral or jugular vein, providing

[104] Palladini G et al. Management of AL amyloidosis in 2020. Blood 2020; 136:2620–2627.

[105] Palladini et al., J Clin Oncology 2012.

[106] Comenzo et al. Leukemia 2012.

[107] Nin, N. et al. Severe hypercapnia and outcome of mechanically ventilated patients with moderate or severe acute respiratory distress syndrome. Intensive Care Med 43, 200–208 (2017).

partial ventilatory lung support independent of the lungs as an alternative or supplement to invasive mechanical ventilation. The applicant stated that the Hemolung RAS removes up to 50% of basal metabolic carbon dioxide (CO_2) production at circuit blood flows of 350–550 mL/min. According to the applicant, the Hemolung RAS is not intended to provide therapeutic levels of oxygenation. The applicant stated that during the Hemolung RAS therapy, blood passing through the circuit is oxygenated; however, at low extracorporeal blood flows, the limited oxygen-carrying capacity of blood precludes meaningful oxygenation of mixed venous blood. The applicant explained that extracorporeal therapy with the Hemolung RAS requires continuous systemic anticoagulation with unfractionated heparin or a standard of care alternative to prevent clotting of blood in the circuit.

With respect to the newness criterion, the applicant stated that the Hemolung RAS received Breakthrough Device Designation from FDA in 2015 specific to COPD patients experiencing acute, refractory, hypercapnic respiratory failure. The applicant stated it is not applying under the Breakthrough Device Alternative Pathway in the current application for new technology add-on payments, as the Breakthrough Device indication is different from its FDA De Novo indication. The applicant explained that the Hemolung RAS was classified as a Class III device and received a Breakthrough Device designation for COPD only. According to the applicant, on April 22, 2020, the Hemolung RAS received an Emergency Use Authorization (EUA) to treat lung failure due to COVID–19 when used as an adjunct to noninvasive or invasive mechanical ventilation in reducing hypercapnia and hypercapnic acidosis due to COVID–19 and/or maintaining normalized levels of partial pressure of carbon dioxide (PCO_2) and pH in patients suffering from acute, reversible respiratory failure due to COVID–19 for whom ventilation of CO_2 cannot be adequately, safely, or tolerably achieved. The applicant further explained Hemolung RAS was later classified as a Class II device under the De Novo pathway. The applicant indicated its De Novo classification request (DEN210006) was granted on November 13, 2021, for the indication of respiratory support providing extracorporeal carbon dioxide (CO_2) removal from the patient's blood for up to five days in adults with acute, reversible respiratory failure for whom ventilation of CO_2 cannot be adequately or safely achieved using other available treatment options and continued clinical deterioration is expected. According to the applicant, the De Novo classified Hemolung RAS became available on the market on November 15, 2021, the first business day following the FDA authorization. The applicant indicated that it is seeking new technology add-on payments for FY 2023 for the FDA De Novo indication for the treatment of hypercapnic respiratory failure due to all causes in adults, which would include the EUA indication for the use of the Hemolung RAS in patients with respiratory failure caused by COVID–19. The applicant stated that the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of the Hemolung RAS: 5A0920Z (Assistance with respiratory filtration, continuous, $ECCO_2R$).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments. According to the applicant, patients experiencing acute, hypercapnic respiratory failure are treated pharmacologically and with non-invasive ventilatory support as a first line treatment. The applicant stated that if these treatments are insufficient to support the failing lungs, escalation of ventilatory support via intubation and invasive mechanical ventilation (IMV) are the only available treatment options. According to the applicant, patients who are intubated and invasively mechanically ventilated are at significant risk for increased morbidity and mortality. The applicant stated that no additional treatments are available if IMV is insufficient to correct refractory hypercapnia and respiratory acidosis, which ultimately lead to cardiopulmonary collapse and death. Furthermore, the applicant stated that no treatment options are available for patients who have a Do Not Intubate (DNI) order.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that the Hemolung RAS has a different mechanism of action compared to existing technologies. According to the applicant, IMV, the only existing technology used to treat acute, refractory, hypercapnic respiratory failure, utilizes positive airway pressure to deliver oxygen and remove CO_2 from the lungs, whereas the Hemolung RAS removes CO_2 directly from the blood, independent of the lungs and allowing the lungs to rest and recover. Thus, the applicant asserted that the Hemolung RAS uses a different mechanism of action when compared to the existing therapeutic option (that is, IMV). The applicant also stated that extracorporeal membrane oxygenation (ECMO) is a rescue therapy for patients experiencing refractory hypoxemic respiratory failure, where insufficient oxygenation is the source of the respiratory failure. However, the applicant stated that ECMO is not suitable, nor FDA-approved, as a treatment for acute, hypercapnic respiratory failure. Therefore, the applicant asserted that ECMO and the Hemolung RAS are fundamentally different technologies used to treat different patient populations.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG when compared to an existing technology, the applicant stated that the Hemolung RAS is assigned to the same MS–DRGs when compared to an existing technology. Per the applicant, the Hemolung RAS is an escalation therapy to be used when current therapies are unable to support a patient's failing lungs and continued clinical deterioration is expected. The applicant noted that MS–DRGs 207 and 208 (Respiratory System Diagnosis with Ventilator Support >96 Hours and Respiratory System Diagnosis with Ventilator Support ≤96 Hours, respectively) relate to the treatment of respiratory failure using mechanical ventilation, so the Hemolung RAS may be assigned to the same MS–DRGs if mechanical ventilation is unable to safely or adequately remove CO_2 from the blood.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that the Hemolung RAS and IMV are both used to treat patients experiencing acute, refractory, hypercapnic respiratory failure due to numerous disease etiologies and pathophysiologies. However, the applicant noted that the Hemolung RAS is indicated for use as an escalation therapy when IMV is unable to safely or adequately remove CO_2 from the blood and continued clinical deterioration is expected.

In summary, the applicant maintained that the Hemolung RAS is not substantially similar to currently available therapies and/or technologies because it uses a new mechanism of

action and therefore the technology meets the ''newness'' criterion.

We stated in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28236 through 28237) that, as noted previously, the applicant received an FDA De Novo classification for the device on November 13, 2021 (with the product becoming commercially available on November 15, 2021), for the FDA De Novo indication that is the subject of this application, for the treatment of hypercapnic respiratory failure due to all causes in adults. This De Novo indication would include use of the product for the indication for which the applicant initially received an EUA from FDA, for the use of the Hemolung RAS in patients with respiratory failure caused by COVID–19. In the FY 2005 IPPS/LTCH PPS final rule, we stated that the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the MS–DRG weights (69 FR 49002). While our policy is, generally, to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market as discussed in prior rulemaking (77 FR 53348), we have noted that data reflecting the costs of products that have received an EUA could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance (86 FR 45159). We refer readers to section II.F.7. of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159 through 45160), for discussion of our solicitation of comments regarding the newness period for products available through an EUA for COVID–19. As discussed in section II.F.4. of the preamble of this final rule, we are continuing to consider the comments we received regarding the newness period for products available through an EUA for COVID–19 as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159), and we welcomed additional comments in the proposed rule.

Therefore, we stated that because data reflecting the costs of the Hemolung RAS used for the indication of COVID–19 could be available beginning with the EUA on April 22, 2020, we questioned whether the newness period for the use of the Hemolung RAS for patients with COVID–19 should begin with the date of EUA issuance, April 22, 2020, while the newness period for the use of Hemolung RAS for patients with other causes of hypercapnic respiratory failure unrelated to COVID–19 should begin on the date of commercial availability of the De Novo classified device, November 15, 2021. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45159 through 45160), under the current regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, a product available only through an EUA would not be eligible for new technology add-on payments. Therefore, cases involving pediatric patients, or cases involving the use of the Hemolung RAS for greater than 5 days, would not be eligible for new technology add-on payment if the Hemolung RAS is approved for new technology add-on payment for the patient population indicated in its FDA De Novo marketing authorization.

We invited public comments on whether the newness period for the Hemolung RAS when used for patients with COVID–19 should begin on April 22, 2020 (the date of its EUA), when the product became available on the market for this indication. We also invited public comments on whether the Hemolung RAS is substantially similar to existing technologies and whether the Hemolung RAS meets the newness criterion.

Comment: The applicant submitted a public comment regarding the newness date for the Hemolung RAS. The applicant stated that the newness period for COVID–19 Hemolung RAS cases should begin on November 15, 2021 (the date of commercial availability of the De Novo classified device), instead of April 22, 2020 (the date of the Hemolung RAS EUA). The applicant indicated that it provided the Hemolung RAS to hospitals free or at cost to swiftly respond to the global pandemic, and that it did not profit from EUA therapies. The applicant stated that additionally, during the EUA period, hospitals were not seeking payment for Hemolung RAS therapy. The applicant stated that, therefore, cost data collected during the EUA period and prior to FDA clearance do not accurately reflect the added cost of Hemolung RAS therapy.

Response: We thank the applicant for its comment. We note that, as discussed in previous rulemaking, the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. While the commenter stated that it provided the Hemolung RAS to hospitals free or at cost, and that hospitals were not seeking payment for the Hemolung RAS therapy during the EUA period, additional information regarding whether hospitals charged for use of the Hemolung RAS therapy between the date of its EUA and the date of commercial availability of the De Novo classified device, and how it impacts whether use of the technology may be reflected in the data, would be helpful in determining that data reflecting the cost of the product did not become available until the date of commercial availability of the De Novo classified device. However, we note that regardless of whether we consider the beginning of the newness period to commence for the use of the Hemolung RAS for patients with COVID–19 on April 22, 2020 (the date of its EUA) or November 15, 2021 (the date of commercial availability of the De Novo classified device), in both cases, the three-year anniversary date would occur after April 1, 2023, and, therefore, the technology would be considered new for this indication for FY 2023. As we discuss elsewhere in this rule, we also recognize that there may be unique considerations associated with determining the start of the newness period for a product available under an EUA prior to receiving FDA approval, and will continue to consider the comments received regarding the newness period for products available through an EUA for COVID–19 for future rulemaking. We consider the beginning of the newness period to commence for the use of the Hemolung RAS for patients with other causes of hypercapnic respiratory failure unrelated to COVID–19 on the date of commercial availability of the De Novo classified device, November 15, 2021. Accordingly, we consider the Hemolung RAS to be new for FY 2023 for use in patients with both COVID–19 and hypercapnic respiratory failure unrelated to COVID–19, and therefore the product meets the newness criterion for all patient populations indicated in its FDA De Novo marketing authorization.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the Hemolung RAS is not substantially similar to existing treatment options and meets the newness criterion.

With respect to the cost criterion, the applicant presented the following analysis. The applicant searched the FY 2019 MedPAR Limited Data Set (LDS) for cases that received ventilator support to identify patients who may

have been eligible for the Hemolung RAS. The applicant reviewed multiple ICD–10–CM and ICD–10–PCS codes related to respiratory failure and hypercapnic disease and determined that two ICD–10–PCS codes were most applicable: 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours) and 5A1945Z (Respiratory ventilation, 24–96 consecutive hours). We noted that, in the applicant's analysis, it listed ICD–10–PCS code 5A1955Z as 5A1935Z (Respiratory ventilation, greater than 96 consecutive hours), but we believed the applicant intended to reference the correct ICD–10–PCS code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours) to correctly map to MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support >96 Hours).

The applicant identified 68,317 cases mapping to MS–DRGs 207 (Respiratory System Diagnosis with Ventilator Support >96 Hours) and 208 (Respiratory System Diagnosis with Ventilator Support <= 96 Hours). MS–DRG 207 contained 24.6% of the cases and MS–DRG 208 contained the remaining 75.4% of cases.

Next, the applicant removed 100% of the inhalation charges and charges associated with a 1-day length of stay (LOS) in the ICU. The applicant explained that it removed the 1 day of routine care plus ICU day charges based on an assumed LOS reduction associated with the use of the Hemolung RAS from relevant cases (as compared to cases without the Hemolung RAS) to estimate the potential decrease in costs as a result of the use of the Hemolung RAS.[108] The applicant then standardized the charges and applied a 4-year inflation factor of 1.281834 or 28.1834%, based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule and correction notice to calculate outlier threshold charges (86 FR 45542). The applicant then added charges for the new technology, which it calculated by dividing the cost of the Hemolung RAS by the national average CCR for inhalation therapy, which is 0.147 (86 FR 44966).

The applicant calculated a final inflated average case-weighted standardized charge per case of $178,436, which exceeded the average case-weighted threshold amount of $102,867. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the Hemolung RAS meets the cost criterion.

After review of the cost analysis provided by the applicant, we questioned whether the analysis should have included patients who would also require a tracheostomy, which could result in cases mapping to the Pre-Major Diagnostic Category (Pre-MDC) MS–DRGs 003 or 004 if used with mechanical ventilation, and whether the inclusion of those additional MS–DRGs would impact the cost analysis. We sought comments on whether the Hemolung RAS meets the cost criterion.

Comment: The applicant submitted a public comment and updated cost criterion analysis, which included a subset of cases in MS–DRG 003 and MS–DRG 004 in response to our concerns. The applicant stated that cases mapping to these MS–DRGs included non-extracorporeal membrane oxygenation (ECMO) cases with a tracheostomy, receiving mechanical ventilation, and with a primary diagnosis code for hypercapnia or chronic obstructive pulmonary disease (COPD). The applicant followed the same methodology as its original analysis and stated that even when including the subset of cases in MS–DRGs 003 and 004, the case-weighted standardized charges exceed the threshold amount, and the Hemolung RAS meets the cost criterion.

Response: We appreciate the applicant providing an updated cost criterion analysis that includes a subset of patients who would also require a tracheostomy, which resulted in cases mapping to the Pre-Major Diagnostic Category (Pre-MDC) MS–DRGs 003 or 004 if used with mechanical ventilation. Based on the information provided by the applicant, because the final inflated average case-weighted standardized charge per case exceeded the case-weighted threshold amount in all scenarios presented by the applicant, we agree with the applicant that the Hemolung RAS meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the Hemolung RAS offers a treatment option for patients unresponsive to non-invasive mechanical ventilation (NIV), patients unresponsive to invasive mechanical ventilation (IMV), and patients ineligible for currently available treatments (that is, failure of NIV with DNI order). Further, the applicant asserted that the Hemolung RAS significantly improves clinical outcomes relative to available services or technologies.

With regard to the claim that the Hemolung RAS offers a treatment option for patients unresponsive to NIV, the applicant noted that while acute respiratory failure can often be treated with NIV, which does not require intubation and is typically safe and well tolerated, 12–50% of patients are unresponsive to NIV as a result of several factors, including elevated respiratory rates, uncorrected respiratory acidosis, and reduced level of consciousness.[109] [110] [111] Further, the applicant stated that if a patient fails NIV, the only currently indicated treatment is escalation to IMV; however, per the applicant, intubation and IMV following NIV failure is associated with a 200% increase in mortality compared to patients successfully treated with NIV; 27% vs 9% mortality rate, respectively.[112]

The applicant asserted that the Hemolung RAS can be an effective tool for patients unresponsive to NIV by rapidly correcting respiratory acidosis (pH and arterial partial pressure of carbon dioxide ($PaCO_2$)), thereby reducing respiratory drive and improving NIV efficacy. In support of this claim, the applicant submitted a consensus paper by Combes et al.[113] In this consensus paper, 14 clinical experts in critical care and respiratory support using $ECCO_2R$ convened to determine how $ECCO_2R$ therapy is applied, identify how patients are selected, and discuss how treatment decisions are made. Per the applicant, the results of the paper showed that there were two groups of patients where $ECCO_2R$ therapy was indicated—patients with acute respiratory distress syndrome (ARDS) or patients with COPD. The treatment goal for $ECCO_2R$ therapy in patients with ARDS is to provide ultra-protective lung ventilation via managing CO_2 levels. The criteria for initiating $ECCO_2R$ therapy in patients with ARDS and on NIV is when there was no decrease in $PaCO_2$ and no decrease in respiratory rate. In patients with acute

[108] Tiruvoipati, et al., ''Effects of Hypercapnia and Hypercapnic Acidosis on Hospital Mortality in Mechanically Ventilated Patients:'' *Crit Care Med.* Vol 456(7). e649–e656

[109] Conti, V. et al. Predictors of outcome for patients with severe respiratory failure requiring noninvasive mechanical ventilation. Eur Rev Med Pharmacol Sci 19, 3855–3860 (2015).

[110] Bott, J. et al. Randomised controlled trial of nasal ventilation in acute ventilatory failure due to chronic obstructive airways disease. Lancet 341, 1555–1557 (1993).

[111] Phua, J., Kong, K., Lee, K.H., Shen, L. & Lim, T.K. Noninvasive ventilation in hypercapnic acute respiratory failure due to chronic obstructive pulmonary disease vs. other conditions: effectiveness and predictors of failure. Intensive Care Med 31, 533–539 (2005).

[112] Chandra, D. et al. Outcomes of noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease in the United States, 1998–2008. Am. J. Respir. Crit. Care Med. 185, 152–159 (2012).

[113] Combes, A. et al. $ECCO_2R$ therapy in the ICU: consensus of a European round table meeting. Critical Care 24, (2020).

COPD exacerbation, treatment targets were patient comfort, pH between 7.30–7.35, respiratory rate less than 20–25 breaths per minute, decrease of $PaCO_2$ by 10–20%, weaning from NIV, decrease in bicarbonate levels (HCO_3), and maintaining hemodynamic stability. The clinical experts came to the consensus that $ECCO_2R$ therapy may be an effective support treatment for adults with ARDS or COPD exacerbation, but noted the need for further evidence from randomized clinical trials and/or high quality prospective studies to better guide decision-making.

The applicant also submitted three peer-reviewed publications in support of this claim. First the applicant cited Bonin et al.,[114] a case study of a 50-year-old male awaiting a bilateral lung transplant, admitted for COPD exacerbation caused by infection. The patient was initially treated with antibiotics and continuous NIV, which he tolerated for three days. After three days, the patient decompensated due to a spontaneous pneumothorax. The lung was emergently reinflated, but the patient's respiratory status continued to decline with a $PaCO_2$ between 72–85 mmHg, pH of less than 7.3, and a respiratory rate of 30–40. The patient showed signs of exhaustion but did not qualify for intubation due to the recent pneumothorax. The patient consented to the Hemolung RAS therapy and within the first hour of treatment, the patient's respiratory rate improved to around 10 breaths/minute. However, the patient was no longer able to tolerate the NIV minimum set breathing rate, so the minimum set breathing rate was turned off. The $PaCO_2$ decreased to 55–60 mmHg for the duration of therapy (6 days). The patient was able to be successfully weaned from continuous NIV. The patient was also able to take oral nutrition and participate in interventions against pressure sores. After day 6, the patient was able to wean from the Hemolung RAS support and continue with intermittent NIV support.

Second, the applicant cited a multi-national pilot study done by Burki et al.[115] in India and Germany. There were 20 COPD patients with hypercapnic respiratory failure treated with ECCO2R therapy and placed into 1 of 3 groups. Group 1 had seven patients on NIV with a high likelihood of requiring IMV; Group 2 had two patients who could not be weaned from NIV; and Group 3 had 11 patients on IMV who failed weaning attempts. The authors found that the device was well-tolerated with complications and rates similar to those seen with central venous catheterization. The patients in Group 1 successfully avoided IMV as a result of $ECCO_2R$ therapy, although three patients died within 30 days of $ECCO_2R$ therapy due to underlying disease states. The patients in Group 2 were successfully weaned from continuous NIV after receiving $ECCO_2R$ therapy and were alive 30 days after $ECCO_2R$ therapy, but remained on intermittent non-invasive, positive-pressure ventilation (NIPPV) support. Of the patients in Group 3, nine of the 11 patients had been on IMV for greater than 15 days prior to $ECCO_2R$ therapy. In Group 3, three patients were weaned from IMV, three patients had decreased IMV support, one patient expired from retroperitoneal bleed following catheterization, and one patient remained on the same level of ventilatory support despite receiving $ECCO_2R$ therapy. The authors concluded that the single catheter, low-flow $ECCO_2R$ system, provided clinically useful levels of CO_2 removal in patients with COPD and could be a potentially valuable addition to the treatment of hypercapnic respiratory failure.

Third, the applicant cited a case series by Tiruvoipati et al. (2016),[116] which retrospectively reviewed 15 patients among three Australian ICUs treated with the Hemolung RAS who had severe hypercapnic respiratory failure due to COPD, ARDS, asthma, or bronchiolitis obliterans syndrome (BOS), to show that $ECCO_2R$ was safe and effective in the removal of CO_2. For five patients (four with COPD and one with BOS), the indication for the Hemolung RAS was to avoid intubation, whereas for the other 10 patients (five with acute lung injury/ARDS, three with asthma, and two with COPD), the indication was to institute lung-protective ventilation. The median age of the patients was 61.5 years; 12 patients were men, the median Acute Physiology and Chronic Health Evaluation III (APACHE III) score was 85, and the median duration of $ECCO_2R$ was 5 days. The primary outcome measures of the study were clearance of CO_2 and change in pH with the use of $ECCO_2R$. Secondary outcome measures included complications associated with Hemolung RAS use, survival to weaning from the Hemolung RAS, and survival to ICU and hospital discharge. There was no specified protocol for managing mechanical ventilation across the three centers; however, all centers used low-pressure ventilation for ARDS. For asthma, the mechanical ventilation was characterized by low tidal volume, low respiratory rate, and short inspiratory time associated with prolonged expiratory time to avoid dynamic hyperinflation. Four of the five patients treated for this indication, as well as all 10 patients who were treated to institute lung-protective ventilation, avoided intubation; successful lung-protective ventilation was achieved by a reduction in peak inspiratory pressure, tidal volume, and minute ventilation. The clearance of CO_2 and return of $PaCO_2$ to near-normal levels was achieved within 6 hours, and there was significant reduction in minute ventilation and peak airway pressures. Complications reported during the study included hemorrhage, thrombocytopenia, and compartment syndrome, none of which required cessation of the Hemolung RAS therapy. Overall, 93.3% of the patients survived to discontinuation of $ECCO_2R$, 73.3% of patients survived to ICU discharge, and 66.66% of patients survived to hospital discharge. In conclusion, the study authors stated that the Hemolung RAS appears to be safe and effective for managing hypercapnic respiratory failure of various etiologies, but noted that more research is needed to clarify which patients may benefit most from this therapy.

In addition to the previous peer-reviewed studies, the applicant also cited the Hemolung RAS Registry Program Analysis in support of its claim.[117] Per the applicant, the voluntary Hemolung RAS Registry Program collected data from commercial use of the Hemolung RAS outside of the US as well as US EUA therapies. 176 patients from the Hemolung RAS Registry were analyzed to evaluate the benefits and safety of the Hemolung RAS therapy. The applicant stated that the Hemolung RAS Registry Program Analysis demonstrated that 86% (19/22) of patients failing NIV avoided

[114] Bonin, F., Sommerwerck, U., Lund, L. & Teschler, H. Avoidance of intubation during acute exacerbation of chronic obstructive pulmonary disease for a lung transplant candidate using extracorporeal carbon dioxide removal with the Hemolung. The Journal of Thoracic and Cardiovascular Surgery 145, e43–e44 (2013).

[115] Burki, N. et al. A novel extracorporeal CO_2 removal system: Results of a pilot study of hypercapnic respiratory failure in patients with COPD. Chest 143, 678–686 (2013).

[116] Tiruvoipati, R. et al. Early experience of a new extracorporeal carbon dioxide removal device for acute hypercapnic respiratory failure. Crit Care Resusc 18, 261–269 (2016).

[117] Alung, Inc., HL–CA–1600, Hemolung RAS Registry. A Retrospective Registry Involving Voluntary Reporting of De-identified, Standard of Care Data Following the Commercial Use of the Hemolung Respiratory Assist System (RAS). *ClinicalTrials.gov*. Retrieved December 21, 2021, from Hemolung RAS Registry Program—Full Text View—*ClinicalTrials.gov*.

intubation due to the Hemolung RAS therapy.

With respect to the applicant's assertion that the Hemolung RAS offers a treatment option for patients unresponsive to IMV and are retaining CO_2, the applicant stated that the Hemolung RAS de-couples CO_2 removal from the mechanical ventilator thereby allowing correction of hypercapnia and hypercapnic acidosis without a dangerous escalation of ventilator settings. The applicant provided 10 publications that document the use of the Hemolung RAS in patients unresponsive to IMV to significantly reduce ventilator settings to lung safe levels or to significantly correct and control hypercapnic acidosis, including Tiruvoipati et al. (2016) [118] and Combes et al.,[119] discussed previously.

In the first case study, a 44-year-old male with acute asthma exacerbation went into respiratory arrest and was intubated in the emergency department (ED).[120] The patient was found to have a left tension pneumothorax, which was decompressed, and then developed a second tension pneumothorax on the right side, which was also decompressed. The patient was transferred to the ICU for further management. The patient continued to deteriorate over the subsequent 48 hours due to subcutaneous emphysema and ongoing air leaks, and after 72 hours had uncontrollable hypercapnia ($PaCO_2$ 73, pH 7.22) despite optimal medical management with corticosteroids, nebulized and intravenous bronchodilators, magnesium, ketamine, and muscle relaxants. $ECCO_2R$ was indicated for hypercapnia and to facilitate de-escalation of IMV. After initiating $ECCO_2R$, it was possible to decrease the support on the IMV while maintaining satisfactory gas exchange and allowing the withdrawal of muscle relaxants. Within 1 hour of initiation of $ECCO_2R$, the pH improved from 7.22 to 7.28, and the $PaCO_2$ went from 68.1 to 60.6. The patient remained on $ECCO_2R$ for a total of 7 days mainly due to ongoing air leaks from three chest drains and a bleeding complication that was managed with transfusion. After discontinuing $ECCO_2R$ therapy, the patient received a tracheostomy to assist in weaning from IMV. The patient was successfully weaned from IMV after 23 days in the ICU and was ultimately discharged home. The authors discussed that while this patient could have been treated with ECMO, the use of ECMO is limited to specialized centers and requires a multidisciplinary approach for a successful outcome.

In the second case study, the Hemolung RAS system was used to treat hypercapnia in a 58-year-old male patient with an out-of-hospital cardiac arrest where mechanical ventilation failed to achieve normocapnia.[121] The patient was intubated in the ED and treated with nebulized bronchodilators, corticosteroids, and therapeutic hypothermia. Initially, the $PaCO_2$ was 82 mmHg (baseline 50 mmHg) with a pH of 7.20, but as the next few hours progressed, the patient became more difficult to ventilate and the $PaCO_2$ increased to 94 mmHg. $ECCO_2R$ therapy was indicated to prevent lung injury and secondary brain injury. After initiating the Hemolung RAS, the minute ventilation and the respiratory rate could be decreased and the team was able to optimize the inspiratory and expiratory time ration to minimize the risk of barotrauma. The patient was on the Hemolung RAS therapy for 3 days and was able to de-escalate the ventilator settings, but still required mechanical ventilation. After cessation of the Hemolung RAS therapy, the patient started to show signs of significant hypoxic brain injury. Despite maximal medical treatment, the neurological prognosis was considered to be very poor, and all life-sustaining therapies were withdrawn. The authors stated that $ECCO_2R$ therapy is safe to use in a metropolitan hospital where the staff have a limited period of education, and that the extracorporeal therapy was delivered without complications. The authors also stated that ECMO is not an option in every health care center since it requires a specialized team including cardiac surgeons and perfusionists and is costly. The authors stated that $ECCO_2R$ is less invasive and able to provide partial respiratory support. Thus, the authors concluded that $ECCO_2R$ may have a role in patients with severe respiratory failure when IMV alone is inadequate and in centers that are not capable of initiating ECMO in the management of severe hypercapnic respiratory failure.

Next, the applicant cited a United Kingdom case study about a 48-year-old male presenting to the ED with 7 days of cough, fever, and shortness of breath.[122] He tested positive for COVID–19 via respiratory viral swab and had a chest x-ray demonstrating bilateral infiltrates. He initially required supplemental oxygen via facemask and oral doxycycline to treat possible bacterial co-infection. He continued to deteriorate, was trialed on NIV and failed, and was then transitioned to IMV on day four of the hospitalization and transferred to the ICU for further management. The patient continued to deteriorate and within a week and was found to be in ARDS due to COVID–19 pneumonitis. The patient was treated with several strategies for lung recruitment, and was referred to ECMO but was declined on the basis of futility. The treatment team believed that continuing to treat the patient with high airway pressure was contributing to the progression of the ARDS, so the Hemolung RAS was initiated as a rescue therapy. After initiation, the $PaCO_2$ and pH improved, which allowed the treatment team to reduce the tidal volume and respiratory rate. The patient spent 6 days on the Hemolung RAS without bleeding events or vasopressors and could continue to receive prone position ventilation without complication. The patient was successfully weaned from the Hemolung RAS and then completed a slow respiratory wean followed by a percutaneous tracheostomy. The patient was ultimately discharged from the ICU to home with mobility and cognition intact. The authors concluded that $ECCO_2R$ can be used as a rescue therapy for patients with hypercapnic respiratory failure resulting from ARDS in COVID–19 pneumonitis and to facilitate lung protective ventilation in patients on IMV. According to the authors, refractory hypercapnia is an acceptable indication for ECMO in ARDS and that $ECCO_2R$ can be considered as rescue therapy if ECMO is deemed inappropriate or cannot be delivered due to resource constraints. Per the authors, potential advantages of using $ECCO_2R$ over ECMO include lack of requirement for transfer to an ECMO center, smaller catheter size, and lower blood flow rate which may reduce the likelihood of complications.

The applicant also cited a case study of an 18-year-old male with solitary mediastinal metastasis and ARDS, in which the Hemolung RAS was used to facilitate de-escalation of mechanical

[118] Tiruvoipati, R. et al. Early experience of a new extracorporeal carbon dioxide removal device for acute hypercapnic respiratory failure. Crit Care Resusc 18, 261–269 (2016).

[119] Combes, A. et al. $ECCO_2R$ therapy in the ICU: consensus of a European round table meeting. Critical Care 24, (2020).

[120] Tiruvoipati R., et al. Low-flow veno-venous extracorporeal carbon dioxide removal in the management of severe status asthmatics: a case report. Clin Respir J. 2014;10(5):653–656.

[121] Tiruvoipati R., et al. Management of severe hypercapnia post cardiac arrest with extracorporeal carbon dioxide removal. Anaesth Intensive Care. 2014;42(2):248–252.

[122] Tully R.P., et al. The successful use of extracorporeal carbon dioxide removal as a rescue therapy in a patient with severe COVID–19 pneumonitis. Anaesthesia Reports 2020; 8:113–115.

ventilation.[123] Post-treatment with chemotherapy, a residual mediastinal mass was found with extension to the left lung hilum. The patient underwent lung resection and was extubated postoperatively without issue. The patient became febrile and developed a progressively extensive right lung infiltrate. On postoperative day five, the patient developed severe hypercapnia, hypoxemia, and hypotension, necessitating re-intubation and invasive mechanical ventilation. The Hemolung RAS was initiated to provide $ECCO_2R$. Arterial PCO_2 decreased from 73 to 53 mmHg within 4 hours (with a concomitant pH increase from 7.28 to 7.44), permitting tidal volume reduction to 3.5 mL/kg, and plateau airway pressure to 25 cm H2O, with simultaneous hemodynamic improvement. $ECCO_2R$ was titrated to maintain an arterial PCO_2 between 45 and 50 mmHg, and the patient was weaned and decannulated after 71 hours of support. The patient was removed from mechanical ventilation within 24 hours and then transferred to an intermediate care unit. No $ECCO_2R$-related complications were observed. The authors stated the Hemolung RAS has a conceptual advantage over ECMO as the Hemolung RAS uses one small dual-lumen venous catheter, without additional arterial access and its attendant risks. The authors concluded that in appropriately selected patients, a minimally invasive $ECCO_2R$ approach may be useful.

Next, the applicant cited a case study by Saavedra-Romero et al.,[124] which describes the use of $ECCO_2R$ immediately administered with lung-protective mechanical ventilation on a patient with COVID–19 ARDS in her mid-60s. The authors stated that, upon arrival to the ICU, on inpatient day 5, the patient's oxygen saturation by pulse oximeter (SpO_2) was 77%, blood pressure (BP) 90/40 on norepinephrine at 10 mcg/min, and the patient's initial arterial blood gas (ABG) results were pH = 7.14, $PaCO_2$ = 90 mmHg, PaO_2 = 52 mmHg, and HCO_3 = 30 mEq/L. The patient had significant whole-body subcutaneous crepitus, and the chest x-ray (CXR) showed an inflated right lung, subcutaneous emphysema, and an appropriately positioned endotracheal tube (ETT). The patient became increasingly tachycardic and tachypneic due to further worsening of hypercapnia and respiratory acidosis. $ECCO_2R$ was initiated using the Hemolung RAS and was administered for 17 days without complications. Ventilator settings were maintained at PEEP of 14, rate of 26, and minute ventilation at 7.8 liters during the first 24 hours. Respiratory rate and tidal volumes were subsequently titrated downward, maintaining adequate oxygen levels and permissive hypercapnia. The patient's chest tubes were removed 4 days after the Hemolung RAS decannulation, and the patient was weaned from mechanical ventilation 28 days from ICU admission, and discharged 47 days after admission. The authors stated that this case report highlights the use of $ECCO_2R$ to facilitate effective treatment of a patient with severe hypercapnic respiratory failure secondary to COVID–19 ARDS and multiple risk factors for death. The authors stated that treatment with $ECCO_2R$ allowed a lung-protective ventilator management strategy with ultralow tidal volumes, minimizing the risk of ventilator-induced lung injury, attenuating severe hypercapnia and acidosis, and limiting the expansion of an existing pneumothorax. The authors concluded that $ECCO_2R$ facilitates early lung-protective ventilation and control of refractory hypercapnia and can be safely utilized to increase the likelihood of survival among patients with severe COVID–19 ARDS.

Finally, the applicant cited a case study by Bermudez et al.,[125] in which a 33-year-old male with cystic fibrosis (CF), post double lung transplantation who developed severe hypercarbic respiratory failure due to adenovirus pneumonia requiring hospitalization, tracheostomy, and prolonged IMV for greater than 30 days. The patient was transferred to a tertiary care center and was treated with the Hemolung RAS because of persistent hypoxemia and hypercarbia. The patient was not a candidate for ECMO because of frail clinical condition, volume overload, and need for a redo lung transplantation. After 4 days of the Hemolung RAS support, the patient was weaned from vasopressors, and after 9 days, the patient was accepted as a candidate for redo lung transplantation because of considerable clinical improvement.

Lastly, the applicant provided a retrospective, multicenter study of 31 patients placed on the Hemolung RAS at 8 sites across the U.S.[126] The cohort was comprised of patients with COVID–19 who were mechanically ventilated with severe hypercapnia and respiratory acidosis and treated with low-flow extracorporeal CO_2 removal treated between March 4 and September 30, 2020. Two patients underwent cannulation but were never started on therapy due to a vascular access failure in one patient and immediate circuit clotting in the other. For the 29 patients who received the Hemolung RAS treatment, analysis of covariance revealed a significant improvement trend in both pH and $PaCO_2$ ($p < 0.0001$). Comparison of time intervals yielded a statistically significant improvement in pH (7.24 ± 0.12 to 7.35 ± 0.07; $p < 0.0001$) and decrease in PCO_2 (79 ± 23 to 58 ± 14; $p < 0.0001$) from baseline to 24 hours after start of therapy. There were numerical, but not significant, decreases from baseline to 24 hours in respiratory rate (26.6 ± 5.4 to 23.4 ± 4.9), tidal volume (407 ± 100 to 386 ± 75 mL), and minute ventilation (10.2 ± 3.2 to 8.7 ± 2.2 L/min). The authors indicated that this is the first reported use of $ECCO_2R$ in the U.S. for this patient population. The authors reported that limitations of the study are its small size and single-cohort retrospective nature. The applicant stated that the study results demonstrated the efficacy of $ECCO_2R$ using the Hemolung RAS to improve respiratory acidosis in patients with severe hypercapnic respiratory failure due to COVID–19.

In addition to the case reports and retrospective study, the applicant also cited to the Hemolung RAS Registry Program Analysis, discussed previously, in support of its claim.[127] The applicant stated that the Hemolung RAS Registry Program Analysis demonstrated clinically and statistically significant correction of pH and $PaCO_2$ within the first day of the Hemolung RAS therapy ($p<0.05$).[128] Additionally, the applicant noted that the statistical analysis showed this correction in pH and $PaCO_2$

[123] Akkanti B., et al. Low-flow extracorporeal carbon dioxide removal using the Hemolung Respiratory Dialysis System® to facilitate lung-protective mechanical ventilation in acute respiratory distress syndrome. J Extra Corpor Technol. 2017;49(2):112–114.

[124] Saavedra-Romero R., et al. Treatment of Severe Hypercapnic Respiratory Failure Caused by SARS–CoV–2 Lung Injury with $ECCO_2R$ Using the Hemolung Respiratory Assist System. Case Reports in Critical Care 2021; 1–5.

[125] Bermudez, et al. ''Prolonged Use of the Hemolung Respiratory Assist System as a Bridge to Redo Lung Transplantation'' Annals of Thorac Surg. 2015 Vol 100 (6). P. 2330–2333.

[126] Akkanti B., et al. Physiologic Improvement in Respiratory Acidosis Using Extracorporeal CO_2 Removal With Hemolung Respiratory Assist System in the Management of Severe Respiratory Failure From Coronavirus Disease 2019. Critical Care Explorations. 2021;3:e0372.

[127] Alung, Inc., HL–CA–1600, Hemolung RAS Registry. A Retrospective Registry Involving Voluntary Reporting of De-identified, Standard of Care Data Following the Commercial Use of the Hemolung Respiratory Assist System (RAS). *ClinicalTrials.gov*. Retrieved December 21, 2021, from Hemolung RAS Registry Program—Full Text View—*ClinicalTrials.gov*.

[128] Ibid. *ClinicalTrials.gov*. Retrieved December 21, 2021, from Hemolung RAS Registry Program—Full Text View—*ClinicalTrials.gov*.

was independent of the patient's primary diagnosis.

With respect to the applicant's assertion that the Hemolung RAS offers a treatment option for patients ineligible for currently available treatments (for example, patients with a DNI order), the applicant reiterated that intubation with IMV is the only currently available treatment option for patients failing NIV; however, the applicant indicated that these patients have no other therapeutic options if they were to fail NIV because of their preference to not be intubated. According to the applicant, the CO_2 removal by the Hemolung RAS would rapidly correct the pH and $PaCO_2$ which would reduce the respiratory drive and improve NIV efficacy and prevent continued clinical deterioration.[129] [130]

The applicant submitted three peer-reviewed case reports that have documented the use of the Hemolung RAS in patients failing NIV with a DNI order. In the first case study done in Germany,[131] a 72-year-old female with a past medical history of severe COPD (GOLD 4, nocturnal home ventilation therapy) with a DNI order presented to an ED in a hypercapnic coma. The patient had a Glasgow Coma Score of 3, pH of 6.97, and $PaCO_2$ greater than 150 mmHg. The patient was hemodynamically stable on NIV with a respiratory rate of 28, oxygen saturation of 88% on supplemental oxygen with an inspired fraction (FiO_2) of 30%. After 30 minutes of NIV treatment, the patient's $PaCO_2$ improved, but the patient was nearly unconscious and was transferred to the ICU. Because of the high predictive mortality for patients with severe COPD who fail NIV and require intubation and invasive mechanical ventilation, combined with the patient's DNI order, the Hemolung RAS was initiated to supplement treatment. Within the first hour of treatment with both NIV and Hemolung RAS, the $PaCO_2$ levels continued to decrease from 109 mmHg to 89 mmHg and the patient's level of consciousness improved after about 25 minutes. Ultimately, the patient was able to start oral nutrition, communicate, and start mobilizing early because of her improved mental state within four hours of starting the Hemolung RAS and was discharged to rehabilitation.

The second case study by Mani et al. described two patients with severe COPD admitted to the ICU with an acute COPD exacerbation requiring NIV, but failed NIV treatments.[132] A 69-year-old female in India was admitted with acute COPD exacerbation, waning consciousness and a pH of 7.20 and $PaCO_2$ of 101 mmHg. After starting NIV for 2 hours, the $PaCO_2$ had risen to 105 mmHg and pH had dropped to 7.193. After 1 hour of the Hemolung RAS treatment and NIV, the $PaCO_2$ declined to 93 mmHg with a pH 7.25. After 6 hours of treatment with the Hemolung RAS and NIV, the patient was awake with a $PaCO_2$ of 68 mmHg and a pH of 7.35. Ultimately, she was discharged to home on home oxygen and nocturnal NIV. There was also a report of a 78-year-old male with COPD and other comorbidities who had a DNI order in Germany. He was admitted with an acute COPD exacerbation and treated with NIV after his initial arterial blood gas (ABG) showed $PaCO_2$ 92 mmHg and pH of 7.24. After treatment with both the Hemolung RAS and NIV for 1 hour, the patient's $PaCO_2$ dropped to 68 mmHg and pH 7.33. Ultimately, the patient was discharged to home on nocturnal NIV. Both patients were both diagnosed with thrombocytopenia as a known complication of extracorporeal therapy, but neither required transfusion.

The applicant submitted a third case study in which Cole et al. describe a 62-year-old female with past medical history of COPD (GOLD class 3) and 2 recent hospitalizations for COPD exacerbations in the past 60 days.[133] The patient had hypercapnic respiratory failure for which she did not want to be intubated, so she was started on NIV. She initially improved, but by day four of NIV treatment, she deteriorated, as evidenced by tachypnea and fatigue due to increased work of breathing. She was started on the Hemolung RAS and within two hours therapy with the Hemolung RAS alone (patient requested to stop NIV with the initiation of the Hemolung RAS), the patient's respiratory rate improved. Within 6 hours, the patient was able to converse and fully engage with her treatment. Ultimately the patient was discharged to home at her baseline activity level and did not require home oxygen therapy, and was not readmitted to hospital within 30 days of discharge.

Furthermore, the applicant claimed that the Hemolung RAS significantly improves clinical outcomes relative to services or technologies previously available by mitigating the harmful clinical sequelae from hypercapnic acidosis and facilitates de-escalation of high pressure and high volume ventilatory support or prevent intubation, both of which are known predictors for poor clinical outcomes. Thus, per the applicant, the correction of hypercapnia and hypercapnic acidosis (that is, pH and $PaCO_2$) are appropriate surrogate markers for improved clinical outcomes in critically ill, mechanically ventilated patients. Per the applicant, the use of correction of hypercapnia and hypercapnic acidosis as surrogate markers for improved clinical outcomes was accepted by FDA as evidence of the clinical benefit of the Hemolung RAS as part of FDA's clearance of its De Novo request.

The applicant asserted that the pH and $PaCO_2$ correction due to the Hemolung RAS therapy provide the following six improved outcomes: (1) reduced mortality in intubated and IMV patients; (2) reduced length of stay in IMV patients; (3) de-escalation of mechanical ventilation settings (decreased rate of subsequent diagnostic or therapeutic interventions); (4) avoidance of intubation following NIV failure; (5) reduced mortality in NIV patients; and (6) improvement in activities of daily living/quality of life.

In support of its assertion that the Hemolung RAS reduces mortality in intubated and IMV patients, the applicant cited two background studies.[134] [135] In the study by Nin et al., the authors completed a secondary analysis of 3 prospective, non-interventional cohort studies in 1,899 patients with ARDS among 40 ICUs. The goal of the study was to determine the relationship between severe hypercapnia ($PaO_2 \geq 50$ mmHg) in the first 48 hours following onset of ARDS and mortality. The applicant stated that the study results demonstrate that severe hypercapnia in IMV patients was independently associated with increased risk of ICU mortality (odds

[129] Burki, N. et al. A novel extracorporeal CO_2 removal system: Results of a pilot study of hypercapnic respiratory failure in patients with COPD. Chest 143, 678–686 (2013).

[130] Tiruvoipati, R. et al. Early experience of a new extracorporeal carbon dioxide removal device for acute hypercapnic respiratory failure. Crit Care Resusc 18, 261–269 (2016).

[131] Engel, M., Albrecht, H. & Volz, S. Use of Extracorporeal CO_2 Removal to Avoid Invasive Mechanical Ventilation in Hypercapnic Coma and Failure of Noninvasive Ventilation. J Pulm Respir Med 6, 1–3 (2016).

[132] Mani, R.K., Schmidt, W., Lund, L.W. & Herth, F.J.F. Respiratory dialysis for avoidance of intubation in acute exacerbation of COPD. ASAIO J 59, 675–678 (2013).

[133] Cole, S. et al. Extracorporeal carbon dioxide removal as an alternative to endotracheal intubation for noninvasive ventilation failure in acute exacerbation of COPD. J Int Care Soc 15, 344–346 (2014).

[134] Nin, et al., ''Severe hypercapnia and outcome of mechanically ventilated patients with moderate or severe acute respiratory distress syndrome'' Intensive Care Med. 2017. p. 200—208.

[135] Tiruvoipati, et al., ''Effects of Hypercapnia and Hypercapnic Acidosis on Hospital Mortality in Mechanically Ventilated Patients'' Crit Care Med. 2017. Vol 456(7). e649–e656.

ratio: 1.93, 95% CI: 1.32–2.81, p = 0.001). The second study by Tiruvoipati et al. (2017), was a multicenter, binational, retrospective study that included 252,812 patients of 3 cohorts: normocapnia and normal pH (n = 110,104), compensated hypercapnia (n = 20,463), and hypercapnic acidosis (n = 122,245), that aimed to determine the relationship between these states and Acute Physiology and Chronic Health Evaluation (APACHE) III score and mortality. The study found that those with compensated hypercapnia and hypercapnic acidosis had higher APACHE III scores (49.2 vs. 53.2 vs. 68.6, p<0.01); mortality was highest in the hypercapnic acidosis patients (OR: 1.18, 95% CI: 1.1–1.25) and lowest in the normocapnia and normal pH, p < 0.001. The applicant stated that the adjusted odds ratio for hospital mortality remained significantly higher in compensated hypercapnia and hypercapnic acidosis when compared with patients with normocapnia and normal pH irrespective of their P/F ratios.

In support of the applicant's second assertion that use of the Hemolung RAS contributes to reduced LOS in IMV patients, the applicant cited Tiruvoipati et al. (2017), previously discussed.[136] The median hospital LOS was 10.5 days in the normocapnia and normal pH group, 12 days in the compensated hypercapnia group and 11 days in the hypercapnic acidosis group (p<0.001). The median ICU LOS was 1.9 days vs 2.2 days vs. 2.9 days in the normocapnia/normal pH group vs. compensated hypercapnia group vs. the hypercapnic acidosis group, respectively (p<0.001). The authors noted that that there was increased mortality in patients with hypercapnic acidosis and compensated hypercapnia with unclear cause.

In support of the applicant's assertion that use of the Hemolung RAS results in de-escalation of mechanical ventilation settings and decreased rate of subsequent diagnostic or therapeutic interventions, the applicant cited the Tully et al. case report,[137] discussed previously, in which intubated patients had a 20% decrease in peak airways pressure and 30% decrease in driving pressure during the Hemolung RAS therapy. The applicant also cited the Tiruvoipati et al. (2016) study, discussed previously, in which 10 patients showed a 19% decrease in peak respiratory pressure and a 26% decrease in minute ventilation within 1 day of the Hemolung RAS therapy.[138] The applicant also cited the Hemolung RAS Registry Program Analysis,[139] which demonstrated statistically significant correction of pH and $PaCO_2$ within the first day of the Hemolung RAS therapy (p<0.05).

In support of its assertion that use of the Hemolung RAS contributes to avoidance of intubation following NIV failure, the applicant noted that respiratory acidosis is the primary determinant of NIV failure citing risk charts using a background study from Confalonieri et al.,[140] in which data from 1,033 patients admitted to experienced hospital units was used to predict the likelihood of failure of noninvasive positive pressure ventilation (NPPV). The prediction charts were calculated using the APACHE II, GCS, pH, and respiratory rate data of 1,033 patients admitted with acute respiratory failure due to exacerbation of COPD treated with NIV. The applicant stated that the study results show that pH <7.25 (acidosis) after 2 hours of NIV is the primary determinant of NIV failure [odds ratio: 21.02; 95% CI: 10.07–43.87], and that additionally, a pH between 7.25 and 7.29 (acidosis) after 2 hours of NIV is also significant predictor of NIV failure [odds ratio:2.92; 95% CI: 1.62–5.28]. The applicant stated that accuracy and generalizability of the model's ability to predict NIV failure was validated on an independent group of 145 COPD patients treated with NIV.

In a prospective, single-arm feasibility study, Burki et al., previously discussed, stated that 100% (7/7) patients failing NIV and treated with the Hemolung RAS therapy avoided intubation and 100% (2/2) patients failing NIV with a DNI and treated with the Hemolung RAS therapy were successfully weaned from NIV.[141] The applicant cited a retrospective review by Tiruvoipati et al. (2016), also previously discussed, in which 80% (4/5) of patients failing NIV and treated with Hemolung RAS therapy avoided intubation.[142] Furthermore, the applicant cited an unpublished study of the Hemolung RAS Registry Program Analysis,[143] in which 86% of patients (19 of the 22 patients in the analysis) who failed NIV and were treated with the Hemolung RAS therapy avoided intubation.

In support of the assertion that the Hemolung RAS reduced mortality in NIV patients, the applicant submitted two retrospective studies as background studies, in addition to two case studies that utilized the technology. The first background study [144] was a retrospective analysis of data from the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample between 1998 and 2008 to assess the pattern and NIPPV use for acute exacerbations of COPD. The patient cohort was defined as people greater than 35-years-old admitted with a primary diagnosis of COPD or a primary diagnosis of respiratory failure with a secondary diagnosis of COPD. The study demonstrated a decline over time in overall in-hospital mortality for those patients treated with NIPPV without a subsequent need for IMV. Mortality was high and increased over time in patients who transitioned from NIPPV to IMV (27%) compared to those patients who did not transition (9%). Charges for hospitalization increased from 1998 to 2008, especially for patients who transitioned from NIPPV to IMV. LOS decreased in all patients except those who transitioned from NIPPV to IMV. The authors noted a few limitations that would have allowed for a more detailed examination of predictors of NIPPV failure and death, including the lack of information on the severity of the exacerbation, response to NIPPV treatment, end-of-life decision-making,

[136] Ibid.

[137] Tully R.P., et al. The successful use of extracorporeal carbon dioxide removal as a rescue therapy in a patient with severe COVID–19 pneumonitis. Anaesthesia Reports 2020; 8:113–115.

[138] Tiruvoipati, R., et al. Effects of Hypercapnia and Hypercapnic Acidosis on Hospital Mortality in Mechanically Ventilated Patients*: Critical Care Medicine. 2017;45(7):e649–e656.

[139] Alung, Inc., HL–CA–1600, Hemolung RAS Registry. A Retrospective Registry Involving Voluntary Reporting of De-identified, Standard of Care Data Following the Commercial Use of the Hemolung Respiratory Assist System (RAS). *ClinicalTrials.gov*. Retrieved December 21, 2021, from Hemolung RAS Registry Program—Full Text View—*ClinicalTrials.gov*.

[140] Confalonieri M., et al. A chart of failure risk for noninvasive ventilation in patients with COPD exacerbation. European Respiratory Journal. 2005;25(2):348–355.

[141] Burki N., et al. A novel extracorporeal CO_2 removal system: Results of a pilot study of hypercapnic respiratory failure in patients with COPD. Chest. 2013;143(3):678–686.

[142] Tiruvoipati R., et al. Early experience of a new extracorporeal carbon dioxide removal device for acute hypercapnic respiratory failure. Crit Care Resusc. 2016;18(4):261–269.

[143] The applicant cited an unpublished study using data collected from physicians as part of the Hemolung Registry Program. We believe information regarding the Hemolung Registry Program is available here: Alung, Inc., HL–CA–1600, Hemolung RAS Registry. A Retrospective Registry Involving Voluntary Reporting of De-identified, Standard of Care Data Following the Commercial Use of the Hemolung Respiratory Assist System (RAS). *ClinicalTrials.gov*. Retrieved December 21, 2021, from Hemolung RAS Registry Program—Full Text View—*ClinicalTrials.gov*.

[144] Chandra, et al, ''Outcomes of noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease in the United States, 1998–2008'' Am J. Respir Crit Care Med. 2012. Vol 185 (2). p. 152–159

or location of the patient in the hospital (ICU vs. medical ward vs. ED, etc.).

The applicant also cited a retrospective study by Sprooten et al.[145] as background, that looked at patients admitted to the Respicare Unit located in Maastricht University Medical Center (MUMC) in the Netherlands between 2009 and 2011 who met the criteria of admitted for exacerbation of COPD requiring NIV therapy and a definitive COPD diagnosis. In-hospital mortality was 14% with a median LOS of 16.5 days. Overall, this single-center study showed that patients who are admitted to the hospital for a first hospitalization requiring NIV for acute respiratory due to COPD exacerbation have a high short- and long-term mortality rate. According to the article, older age, NIV use greater than eight days and lack of successful NIV response were independent prognostic factors to two-year mortality rather than response of levels of $PaCO_2$ or pH.

The applicant also cited two case studies where the Hemolung RAS was used to successfully treat patients in hypercapnic respiratory failure caused by COPD. The applicant stated that in these case reports, the Hemolung RAS therapy prevented imminent death in COPD patients with a DNI order who were failing NIV. In a case study by Engel et al., previously described,[146] a 72-year-old female with hypercapnic coma due to COPD exacerbation was administered the Hemolung RAS; after 4 hours, $PaCO_2$, pH, and clinical parameters improved, and the patient was weaned off therapy after 7 days.

In a second study by Mani et al., previously described,[147] the Hemolung RAS was used to treat two patients. The first patient, a 69-year-old female with COPD, was placed on the Hemolung RAS after failing NIV treatment. After 66 hours of treatment, the patient was weaned off the Hemolung RAS, and was discharged home 4 days later. The second patient, a 78-year-old male with COPD, was placed on the Hemolung RAS after failing NIV treatment. After 48 hours of treatment, the patient was weaned off the Hemolung RAS, and was discharged home 10 days later.

In support of the assertion that the Hemolung RAS improves activities of daily living/quality of life, the applicant submitted one randomized controlled trial (RCT) abstract and three case studies. In the RCT abstract by Barrett at al.,[148] 18 patients (median age: 67.5 years) with acute hypercapnic respiratory failure due to exacerbations of COPD were randomized to receive NIV alone or $ECCO_2R$ and NIV. The applicant stated that the study included patients who were at high risk of failing NIV (pH<7.30 after ≥1 hour of NIV). The applicant stated that the control arm continued to be treated with NIV only (n=9) and the test arm was treated with $ECCO_2R$ (n=9). The primary endpoint was the time to cessation of NIV. Secondary outcomes included device tolerance and complications, changes in arterial blood gases (ABGs) and hospital survival. The time to NIV discontinuation was shorter in the $ECCO_2R$ arm (7 hours) vs in the NIV alone arm (24.5 hours), p = 0.004. The study claimed that dyspnea rapidly improved with $ECCO_2R$, but that ICU and hospital LOS were longer with the $ECCO_2R$ group and there was no difference in mortality or functional outcomes at follow-up. The authors concluded that $ECCO_2R$ can be an alternative to NIV for patients who are at risk of failing or cannot tolerate NIV, or for patients in whom a more rapid correction of hypercapnia is desirable.

The applicant referred to three case studies using the Hemolung RAS to treat hypercapnic respiratory failure, to demonstrate improvement in activities of daily living/quality of life. In the case study by Engel et al., previously described,[149] the applicant stated that early mobilization, communication, and nutrition were facilitated with Hemolung therapy. In the Bermudez et al. case study, previously discussed,[150] the Hemolung RAS was successfully used to bridge a patient with COPD to a lung transplantation. The applicant stated that considerable clinical improvement attributed to Hemolung therapy permitted the patient to be awake and mobilized to sit on the edge of the bed. In the Bonin et al. case study, previously discussed,[151] the applicant stated that drinking and recovery from pressure sores were possible by day three of the Hemolung RAS.

After review of the information provided by the applicant, we stated that we had the following concerns regarding whether the Hemolung RAS meets the substantial clinical improvement criterion. We noted that the evidence provided for several of the claims of substantial clinical improvement include small, non-randomized studies without the use of comparators or controls, including case studies, which may affect the ability to draw meaningful conclusions about treatment outcomes from the results of the studies. We stated that the benefits of avoiding intubation or de-escalating IMV settings are described in case studies, but the absence of comparative data may make it more difficult to determine whether there are clinically meaningful changes in these outcomes. We also noted that in the one abstract of an RCT using the Hemolung RAS,[152] although the time to NIV discontinuation was shorter in the $ECCO_2R$ arm than in the NIV alone arm, the ICU and hospital length of stay were longer with the $ECCO_2R$ group and there were no differences in mortality or functional outcomes at follow-up. Additionally, while the applicant stated that the Hemolung RAS results in improved clinical outcomes, such as reducing mortality in NIV patients compared to continuing the patient's previous treatment, given that many of the case studies provided as evidence to support improved clinical outcomes included only one or two patients, it was not clear whether or not the results of these studies are generalizable to the Medicare population. We also noted that several of the case studies, for example, Bonin et al., Mani et al., Tully et al., etc., mentioned by the applicant included patients and cases from outside the U.S., and we questioned if there may be differences in treatment guidelines between these countries that may have affected clinical outcomes. Lastly, we noted that for several of the claims of substantial clinical improvement, the applicant provided

[145] Sprooten, et al. ''Predictors for long-term mortality in COPD patients requiring non-invasive positive pressure ventilation for the treatment of acute respiratory failure'' Clinical Resp J. 2020. Vol 14 (12). p. 1144–1152

[146] Engel, et al. ''Use of Extracorporeal CO_2 Removal to Avoid Invasive Mechanical Ventilation in Hypercapnic Coma and Failure of Noninvasive Ventilation'' J. Pulm & Resp Med. 2016 Vol 6 (3) p.1–3.

[147] Mani, R.K., Schmidt, W., Lund, L.W. & Herth, F.J.F. Respiratory dialysis for avoidance of intubation in acute exacerbation of COPD. ASAIO J. 59, 675–678 (2013).

[148] Barrett, N., et al. A randomized controlled trial of Non-Invasive Ventilation compared with $ECCO_2R$ for Acute Hypercapnic Exacerbations of COPD. ASAIO J. 2021; 67 (Supp 3) Presented at the 32nd Annual ELSO Conference.

[149] Engel, et al. ''Use of Extracorporeal CO_2 Removal to Avoid Invasive Mechanical Ventilation in Hypercapnic Coma and Failure of Noninvasive Ventilation'' J. Pulm & Resp Med. 2016 Vol 6 (3) p.1–3.

[150] Bermudez, et al. ''Prolonged Use of the Hemolung Respiratory Assist System as a Bridge to Redo Lung Transplantation'' Annals of Thorac Surg. 2015 Vol 100 (6). p. 2330–2333.

[151] Bonin, et al. ''Avoidance of intubation during acute exacerbation of chronic obstructive pulmonary disease for a lung transplant candidate using extracorporeal carbon dioxide removal with the Hemolung''. J. Thorac Cardiovac Surg. 2013. Vol 145 (5). e43–e44.

[152] Barrett, N., et al. A randomized controlled trial of Non-Invasive Ventilation compared with $ECCO_2R$ for Acute Hypercapnic Exacerbations of COPD. ASAIO J. 2021; 67 (Supp 3) Presented at the 32nd Annual ELSO Conference.

evidence from background studies that did not utilize the Hemolung RAS to support the use of the technology to improve clinical outcomes. For example, in support of its assertion that the Hemolung RAS reduces mortality in NIPPV patients, the study cited by the applicant only addressed NIPPV as a treatment option to treat exacerbations in patients with COPD, but did not directly address the use of the Hemolung RAS as an intervention.

We invited public comments on whether the Hemolung RAS meets the substantial clinical improvement criterion.

Comment: The applicant submitted comments in response to CMS' concerns in the FY2023 IPPS/LTCH PPS proposed rule (87 FR 28243) regarding whether the Hemolung RAS meets the substantial clinical improvement criterion. In response to our concerns as to whether the results of non-controlled data may affect the ability to draw meaningful conclusions regarding treatment outcomes and the use of background studies to support claims of substantial clinical improvement, the applicant stated that it acknowledges randomized controlled trial (RCT) data is the gold standard and the limitations of non-controlled data, but that large RCTs investigating medical devices in the critical care setting present unique enrollment challenges. The applicant stated that it is currently conducting the VENT–AVOID RCT in the US (''the Trial''—NCT03255057) investigating the use of the Hemolung RAS in COPD patients, which has faced slow enrollment since it began in 2018, with the COVID–19 pandemic further slowing enrollment. The applicant explained that one reason for the slow enrollment is the highly specific inclusion and exclusion criteria required by RCTs, which is typical of COPD trials. The applicant cited a study that evaluated the number of patients who would meet the inclusion criteria commonly used in COPD clinical trials, where the results demonstrated only 17% of the COPD population would meet the inclusion criteria.[153]

The applicant stated that it believes a substantial amount of real-world evidence supports the technology's use, and as such, the background studies (with a combined >200,000 mechanically ventilated patients) are included to provide evidence demonstrating the life-threatening clinical sequelae that result from hypercapnia and respiratory acidosis in critically ill patients, including increased risk of ICU and hospital mortality, and longer ICU and hospital lengths of stay.[154] [155] The applicant stated that it believes the Hemolung evidence submitted to demonstrate substantial clinical improvement reflects the real-world use and the true impact the Hemolung RAS will have on the Medicare population, and that it is clear that providing clinicians with a tool to effectively correct pH and $PaCO_2$ independently of the lungs will have a significant positive impact on the outcomes of acute respiratory failure patients.

In response to our concerns as to whether the results of the Hemolung RAS case studies that included only one or two patients were generalizable to the Medicare population, the applicant stated that the epidemiology of acute respiratory distress and need for mechanical ventilation in older adults is well established. The applicant noted that there is a natural physiologic decline in lung function with age, which makes safely and adequately ventilating older patients, especially those with respiratory disease, challenging. The applicant noted that at generally accepted lung protective ventilation settings, older patients are more susceptible to an accumulation CO_2 due to poor baseline lung function. The applicant also stated that use of the Hemolung RAS in COPD patients is highly generalizable to the Medicare population given that the prevalence of COPD increases with age, and that in COPD patients failing non-invasive ventilation (NIV), avoiding intubation has a substantial mortality benefit (9% vs 27%).[156]

In response to our concern as to whether the potential differences in treatment guidelines between countries of case studies may have affected clinical outcomes, the applicant referenced the consensus guideline in the US and Europe that generally the goal when ventilating patients is to utilize low volumes and pressures, which can result in CO_2 accumulation in the blood. The applicant explained that as CO_2 accumulation is a basic physiologic response to these ventilator settings, patient location does not affect clinical improvements resulting from the Hemolung RAS therapy.

In response to our concern that the ICU and hospital stays were longer with the $ECCO_2R$ group and there were no differences in mortality or functional outcomes at follow-up, the applicant submitted a recently published RCT [157] with additional data and analysis of its study results on LOS. The applicant cited that the ICU and hospital LOS were both 4–5 days longer with $ECCO_2R$ than with NIV, which was due to a longer ICU LOS. The applicant noted that time from ICU discharge to home discharge was equal in both groups. The applicant noted that with NIV, nurse-led weaning occurred 24/7, based around arterial blood gases, respiratory rate and patient preference, and that patients were discharged to the ward during the daytime if they had been off NIV overnight. In addition, the applicant stated that patients who consistently declined NIV were discharged to a ward bed regardless of pH and this will have contributed to the lower ICU length of stay in the NIV arm. The applicant noted that the protocol for patients receiving $ECCO_2R$ did not allow weaning overnight, and there was a median of eight hours from cessation of $ECCO_2R$ to decannulation and unit protocols required a further overnight stay for observation.

The applicant also explained that the study results showed that time to NIV cessation was significantly shorter in the $ECCO_2R$ arm than in the NIV arm (7 hrs. vs 24:30 hrs., $p = 0.004$). The applicant noted that at one-hour post-randomization the pH was significantly higher in the $ECCO_2R$ arm ($p<0.001$), and at 4 hours post randomization the $PaCO_2$ was significantly lower ($p<0.001$) in the $ECCO_2R$ arm, compared to the NIV only arm. The applicant stated that $ECCO_2R$ also resulted in a significant and rapid reduction in subjective discomfort and dyspnea measured using a visual analogue scale (VAS), where a higher score indicates higher subjective discomfort and dyspnea.

Several other commenters also indicated their support for the

[153] Herland K, Akselsen JP, Skjønsberg OH, Bjermer L. How representative are clinical study patients with asthma or COPD for a larger ''real life'' population of patients with obstructive lung disease? Respiratory Medicine. 2005;99(1):11–19. doi:10.1016/j.rmed.2004.03.026.

[154] Nin N., Muriel A., Peñuelas O., et al. Severe hypercapnia and outcome of mechanically ventilated patients with moderate or severe acute respiratory distress syndrome. Intensive Care Med. 2017;43(2):200–208. doi:10.1007/s00134–016–4611–1.

[155] Tiruvoipati R., Pilcher D., Buscher H., Botha J., Bailey M. Effects of Hypercapnia and Hypercapnic Acidosis on Hospital Mortality in Mechanically Ventilated Patients*: Critical Care Medicine. 2017;45(7):e649–e656. doi:10.1097/CCM.0000000000002332.

[156] Chandra D., Stamm J.A., Taylor B., et al. Outcomes of noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease in the United States, 1998–2008. *Am J. Respir Crit Care Med.* 2012;185(2):152–159. doi:10.1164/rccm.201106–1094OC.

[157] Barrett N.A., Hart N., Daly K.J.R., et al. A randomised controlled trial of non-invasive ventilation compared with extracorporeal carbon dioxide removal for acute hypercapnic exacerbations of chronic obstructive pulmonary disease. Ann Intensive Care. 2022;12(1):36. doi:10.1186/s13613–022–01006–8.

Hemolung RAS. A commenter stated that the Hemolung RAS was used in their center and proved to be reliable (removing approximately 80 ccs of CO_2/min) and was well-accepted by staff. The commenter noted that the staff considered it easy to use compared to ECMO, and were generally able to manage it while also managing other ECMO patients. The commenter stated that the Hemolung RAS will occupy an important niche in treating patients with acute hypercapnic respiratory failure, avoiding intubation up front in some patients as well as facilitating weaning off the ventilator in other cases where intubation was necessary initially.

A group of commenters submitted a comment stating that their experience with the Hemolung RAS underscored the importance of this technology in the Medicare population requiring inpatient management of hypercapnic respiratory failure. The commenters stated that IMV not only does not address the underlying clinical condition leading to hypercapnia, but it also compounds it by elevating pressures applied to the lung in an attempt to increase tidal ventilation, which contributes to morbidity and mortality, and that prior to the introduction of the Hemolung, it was the only option available. The commenters stated that they considered the Hemolung RAS a new technology that allows the patient on IMV to be managed with lower pressures instead of higher, earlier removal from mechanical ventilation, or even avoid mechanical ventilation, which the commenter noted is particularly important for patients with a do not intubate order for whom there are no other treatment alternatives. The commenters considered the Hemolung RAS as representing a significant clinical improvement for patients with hypercapnic respiratory failure in the inpatient setting, particularly for Medicare patients due to their age and risk of complications of the current standard of care.

Response: We thank the applicant and other commenters for their comments. Based on the additional information received, we agree with the applicant that the Hemolung RAS represents a substantial clinical improvement over existing technologies because the technology offers a treatment option for hypercapnic respiratory failure due to all causes in adults while avoiding intubation or facilitating extubation. We also agree with the applicant that the Hemolung RAS fills an unmet need for patients ineligible for currently available treatments, such as mechanical ventilation (for example, in patients with a DNI order). The Hemolung RAS provides extracorporeal CO_2 removal from the patient's blood for up to 5 days in adults with acute, reversible respiratory failure for whom ventilation of CO_2 cannot be adequately or safely achieved using other available treatment options and continued clinical deterioration is expected. For this reason, we agree that the Hemolung RAS offers a valuable treatment option for patients at risk for complications from, unresponsive to, and/or ineligible for, mechanical ventilation.

After consideration of the public comments we received, we have determined that the Hemolung RAS meets the criteria for approval for new technology add-on payments. Therefore, we are approving new technology add-on payments for use of the Hemolung RAS for the indications approved under its FDA De Novo marketing authorization for FY 2023. As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28236) consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, a product available only through an EUA would not be eligible for new technology add-on payments. Therefore, cases involving pediatric patients, or cases involving the use of the Hemolung RAS for greater than 5 days, would not be eligible for new technology add-on payments, as they do not fall under the patient population indicated in its FDA De Novo marketing authorization. Cases involving the use of the Hemolung RAS that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code 5A0920Z (Assistance with respiratory filtration, continuous).

In its application, the applicant estimated that the cost of Hemolung RAS is $10,000, which includes the $7,500 cost of the cartridge and the $2,500 cost of the catheter. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of Hemolung RAS is $6,500 for FY 2023.

d. LIVTENCITY™ (Maribavir)

Takeda Pharmaceuticals U.S.A., Inc. submitted an application for new technology add-on payments for LIVTENCITY™ (maribavir) for FY 2023. LIVTENCITY™ is a cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatrics (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) to ganciclovir, valganciclovir, cidofovir, or foscarnet.

According to the applicant, LIVTENCITY™ is the only antiviral therapy indicated to treat post-transplant patients with CMV in solid organ transplant (SOT) and hematopoietic stem cell transplant (HCT). Per the applicant, LIVTENCITY™ provides multi-targeted anti-CMV activity by inhibiting protein kinase UL97 and its natural substrates, which subsequently inhibits CMV DNA replication, encapsidation, and nuclear egress of viral capsids.

The applicant stated that CMV is one of the most common viral infections experienced by transplant recipients, with an estimated incidence rate between 16%–56% in SOT recipients and 30%–70% in HCT recipients.[158] CMV is a beta herpesvirus that commonly infects humans; serologic evidence of prior infection can be found in 40%–100% of various populations.[159] CMV typically resides latent and asymptomatic in the body but may reactivate during periods of immunosuppression. The applicant estimated that there are approximately 200,000 adult transplants per year globally and an estimated 1,435 cases of CMV post-transplant in the Medicare population per year. The applicant stated that in transplant patients, reactivation of CMV can potentially lead to serious consequences including loss of the transplanted organ and, in extreme cases, death.

Per the applicant, there are four FDA-approved therapies for the treatment and/or prevention (that is, prophylaxis) of CMV disease: valganciclovir, ganciclovir, foscarnet, and cidofovir. The applicant stated that ganciclovir and valganciclovir are approved for prevention of CMV disease in transplant recipients and for treatment of CMV retinitis in immunocompromised hosts, including those with Acquired Immune Deficiency Syndrome (AIDS); and foscarnet and cidofovir are approved for treatment of CMV retinitis in AIDS patients. Per the applicant, none of these four therapies are FDA-approved for the treatment of resistant or

[158] Azevedo L, Pierrotti L, Abdala E, et al. Cytomegalovirus infection in transplant recipients. Clinics.2015;70(7):515–523. doi:10.6061/clinics/2015(07)09; World Health Organization (WHO). International Report on Organ Donation and Transplantation Activities—Executive Summary 2018.

[159] Krech U. Complement-fixing antibodies against cytomegalovirus in different parts of the world. Bull WHO. 1973(49):103–106.

refractory CMV infection and disease. The applicant provided a table that included the therapy, transplant type, mechanism of action, approved indications that were CMV-related, and the formulation(s).

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Therapies Indicated in Post-transplant Patients with CMV Infection/Disease				
Therapy	**Valganciclovir**[160]	**Ganciclovir**[161]	**Foscarnet**[162]	**Cidofovir**[163]
Transplant Type	HCT/SOT	HCT/SOT	HCT/SOT	HCT/SOT
Mechanism of Action	Inhibition of viral DNA polymerase (pUL54) activity (inhibits DNA replication)	Inhibition of viral DNA polymerase (pUL54) activity (inhibits DNA replication)	Inhibition of viral DNA polymerase (pUL54) activity (inhibits DNA replication)	Inhibition of viral DNA polymerase (pUL54) activity (inhibits DNA replication)
Approved Indications (CMV-related)	Treatment of CMV retinitis in patients with AIDS (adults) Prevention of CMV disease in kidney, heart, and kidney-pancreas post-transplant patients at high risk (adults) Prevention of CMV disease in kidney and heart transplant patients at high risk (pediatric)	Treatment of CMV retinitis in immunocompromised adult patients, including patients with AIDS Prevention of CMV disease in adult transplant recipients at risk for CMV disease	Treatment of CMV retinitis in patients with AIDS Combination treatment with ganciclovir for patients who have relapsed after monotherapy with either drug	Treatment of CMV retinitis in patients with AIDS
Formulation	Oral	Intravenous	Intravenous	Intravenous

BILLING CODE 4120–01–C

With respect to the newness criterion, the applicant stated that LIVTENCITY™ was granted Breakthrough Therapy, Priority Review, and Orphan Drug designations from FDA, and subsequently received FDA approval for its New Drug Application on November 23, 2021. LIVTENCITY™ is indicated for the treatment of adults and pediatric patients (12 years of age or older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet. Per the applicant, LIVTENCITY™ became commercially available on December 2, 2021. The applicant did not explain the reason for the delay between market authorization and commercial availability. The recommended dosing is 400 mg (two 200 mg tablets) orally twice daily with or without food. The applicant stated that if LIVTENCITY™ is co-administered with carbamazepine, then the dosage is increased to 800 mg twice daily; if co-administered with phenytoin or phenobarbital, the dosage is increased to 1,200 mg twice daily.

According to the applicant, ICD–10–PCS code 3E0DX29 (Introduction of other anti-infective into mouth and pharynx, external approach) may be used to identify administration of LIVTENCITY™ but does not uniquely identify it. The following ICD–10–PCS procedure codes were created to uniquely describe the use of LIVTENCITY™, effective October 1, 2022: XW0DX38 (Introduction of

[160] VALCTE® (valganciclovir) United States Prescribing Information (2018).

[161] CYTOVENE–IV® (ganciclovir) United States Prescribing Information (2018).

[162] FOSCAVIR® (foscarnet) United States Prescribing Information (2017).

[163] VISTIDE® (cidofovir) United States Prescribing Information (2010).

maribavir anti-infective into mouth and pharynx, external approach, new technology group 8), XW0G738 (Introduction of maribavir anti-infective into upper gi, via natural or artificial opening, new technology group 8), and XW0H738 (Introduction of maribavir anti-infective into lower gi, via natural or artificial opening, new technology group 8).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

With respect to the first criterion, whether a technology uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that LIVTENCITY™ targets a different gene locus (pUL97 vs. pUL54) than the existing therapies to treat CMV infection, including those resistant or refractory to conventional therapy. Specifically, LIVTENCITY™ inhibits CMV DNA replication, encapsidation, and nuclear egress of viral capsids through inhibition of pUL97 and its natural substrates. The applicant provided the mechanisms of action for the other existing anti-CMV drugs, namely valganciclovir ganciclovir, foscarnet, and cidofovir in the table previously listed and concluded that LIVTENCITY™ uses a different mechanism of action compared to existing anti-CMV drugs.

With respect to the second criterion, whether a technology is assigned to the same or a different MS–DRG when compared to an existing technology, the applicant stated that LIVTENCITY™ is expected to be assigned to the same MS–DRGs as therapies that are currently used off-label for the treatment of CMV infection or disease.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant noted that there are no other existing therapies indicated to treat the same or similar type of disease or patient population as LIVTENCITY™. The applicant noted that currently available therapies are used off-label to treat patients with refractory or resistant CMV infection or disease. Thus, the applicant maintained that LIVTENCITY™ is indicated to treat a different patient population compared to existing technologies.

In summary, the applicant asserted that LIVTENCITY™ is not substantially similar to other currently available therapies because it uses a new mechanism of action and is indicated to treat a unique patient population and/or disease and, therefore, the technology meets the newness criterion. We invited public comments on whether LIVTENCITY™ is substantially similar to existing technologies and whether LIVTENCITY™ meets the newness criterion. As noted in the proposed rule, the applicant did not explain the reason for the delay between market authorization and commercial availability, and we requested additional information regarding this point.

Comment: The applicant submitted comments in response to CMS' request for additional information on the delay between market authorization and commercial availability of LIVTENCITY™. Per the applicant, between FDA marketing authorization on November 23, 2021 and commercial availability on December 2, 2021, the applicant applied final packaging and labeling and worked to ship the product to specialty pharmacies and distributors as soon as finished goods were available.

Response: We thank the applicant for the additional information regarding the delay between market authorization and commercial availability. We agree with the applicant that the beginning of the newness period for LIVTENCITY™ is December 2, 2021, the date the product became commercially available.

Comment: A commenter agreed that LIVTENCITY™ does not meet the first and third substantial similarity criteria as it stated that there are no other antivirals with a similar mechanism of action and LIVTENCITY™ offers a novel treatment option for patients with no other antivirals currently approved for the treatment of post-transplant CMV refractory to traditional treatments. They agreed with the applicant that LIVTENCITY™ is likely to share the same MS–DRGs as off-label agents currently used for CMV infection or disease.

Response: We thank the commenter for their input. We agree with the commenter that LIVTENCITY™ has a unique mechanism of action and offers a novel treatment option for patients with post-transplant CMV refractory to traditional treatments.

Based on information submitted by the applicant in its comment and as part of its FY 2023 new technology add-on payment application for LIVTENCITY™, as discussed in the proposed rule (87 FR 28258 through 28259) and previously summarized, we believe that LIVTENCITY™ has a unique mechanism of action because it inhibits pUL97, which is involved in terminal DNA processing, including DNA elongation, encapsidation, and nuclear egress of viral capsids, whereas existing therapies inhibit CMV DNA polymerase (pUL54) or the CMV DNA terminase complex (pUL51, pUL56, and pUL89) that is required for viral DNA processing and packaging. We also believe that LIVTENCITY™ is indicated to treat a unique patient population and/or disease, as it is the only FDA-approved antiviral therapy indicated to treat post-transplant patients with CMV disease in solid organ transplant (SOT) and hematopoietic stem cell transplant (HCT). Therefore, LIVTENCITY™ is not substantially similar to existing treatment options and meets the newness criterion. As stated previously, we consider the beginning of the newness period to commence on December 2, 2021 based on information provided by the applicant that the product first became available for sale on that date.

With respect to the cost criterion, the applicant presented the following analysis. To identify patients who may be eligible to receive LIVTENCITY™ as a treatment, the applicant searched the 2019 MedPAR dataset for cases with the following ICD–10–CM codes for CMV and post-transplant SOT and HCT infection. The applicant included inpatient discharges under Medicare fee-for-service (FFS) and excluded Medicare Advantage discharges.

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ICD-10-CM Code	Description
B25	Cytomegaloviral disease
B.25.0	Cytomegaloviral pneumonitis
B25.1	Cytomegaloviral hepatitis
B25.2	Cytomegaloviral pancreatitis
B25.8	Other cytomegaloviral diseases
B25.9	Cytomegaloviral diseases, unspecified
B27.10	Cytomegaloviral mononucleosis without complications
B27.11	Cytomegaloviral mononucleosis with polyneuropathy
B27.12	Cytomegaloviral mononucleosis with meningitis
B27.19	Cytomegaloviral mononucleosis with other complication
T86.03	Bone marrow transplant infection
T86.822	Skin graft infection
T86.892	Other transplanted tissue infection
T86.93	Unspecified transplant organ and tissue infection
T86.23	Heart transplant infection
T86.812	Lung transplant infection
T86.13	Kidney transplant infection
T86.43	Liver transplant infection
T86.33	Heart-lung transplant infection
T86.852	Intestine transplant infection
T86.5	Complications of stem cell transplant

The applicant identified 1,435 claims mapping to 108 MS–DRGs. For MS–DRGs where the case volume was below 11, the applicant imputed a count of 11 cases. The table lists the nine MS–DRGs with the highest volume of cases.

MS-DRG	Description
699	Other Kidney and Urinary Tract Diagnoses with CC
698	Other Kidney and Urinary Tract Diagnoses with MCC
205	Other Respiratory System Diagnoses with MCC
919	Complications of Treatment with MCC
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC
206	Other Respiratory System Diagnoses without MCC
920	Complications of Treatment with CC
166	Other Respiratory System O.R. Procedures with MCC
865	Viral Illness with MCC

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The applicant did not remove charges for a prior technology, as the applicant claimed that any current treatment that is used off-label to treat CMV patients post-transplant SOT and HCT may not be reflected in claims data. The applicant further explained that in cases where an off-label treatment is reflected on the claim, LIVTENCITY™ might be used as a second-line treatment rather than to replace the off-label treatment. The applicant then standardized the charges and applied a 4-year inflation factor of 1.281834 or 28.1834%, based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule and correction notice to update the outlier threshold (86 FR 45542). The applicant added charges for the new technology by dividing the cost of LIVTENCITY™ by the national average CCR for drugs which is 0.187 (86 FR 44966). The applicant estimated the costs of LIVTENCITY™ based on 8-week dosing regimens to complete the full treatment.

The applicant calculated a final inflated average case-weighted standardized charge per case of $508,855 which exceeded the average case-weighted threshold amount of $76,739.

We invited public comments on whether LIVTENCITY™ meets the cost criterion.

We did not receive any comments on whether LIVTENCITY™ meets the cost criterion. Based on the information submitted by the applicant as part of its FY 2023 new technology add-on payment application for LIVTENCITY™, as discussed in the proposed rule (87 FR 28259 through 28260) and previously summarized, the final inflated average case-weighted

standardized charge per case exceeds the average case-weighted threshold amount. Therefore, LIVTENCITY™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that LIVTENCITY™ represents a new treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. To support this claim, the applicant reiterated that there are no existing therapies that are approved by FDA to treat post-transplant patients with refractory or resistant CMV infection or disease. The applicant also asserted that the use of LIVTENCITY™ may significantly improve clinical outcomes by improving efficacy and reducing adverse effects compared to available therapies.

To support the claim of improved efficacy, the applicant cited results from SOLSTICE, a phase III, open-label, randomized controlled trial in which 352 transplant recipients [HCT (n=211) and SOT (n=141)] with refractory [164] or resistant [165] CMV were assigned 2:1 to receive 400 mg of LIVTENCITY™ twice daily (n=235) or investigator-assigned therapy (IAT) with drug-specific dosing (n=117) for 8 weeks, with 12 weeks of follow-up.[166] The choice of specific IAT was at the investigators' discretion and included mono- or combination therapy (≤2 drugs) with intravenous (IV) ganciclovir, oral valganciclovir, IV foscarnet or IV cidofovir, where switching between ganciclovir and valganciclovir was permitted. The median (range) duration of exposure was 57 (2–64) days in the LIVTENCITY™ arm and 34 (4–64) days with IAT. The primary endpoint was the proportion of patients achieving CMV clearance at 8 weeks, and the key secondary endpoint was achievement of CMV clearance [167] and symptom control [168] at the end of week 8, maintained through week 16. With respect to the primary endpoint, the applicant indicated that CMV clearance at 8 weeks was achieved in 55.7% (n=131/235) of the LIVTENCITY™ group and 23.9% (n=28/117) of the IAT group with an adjusted difference of 32.8%, where the results achieved statistical significance [95% CI, 22.8–42.7%, p<0.001]. With respect to the secondary endpoint, the applicant indicated that 18.7% (n=44/235) of the LIVTENCITY™-treated group and 10.3% (n=12/117) of IAT-treated group maintained CMV viremia clearance and symptom control through week 16 (p=0.013).[169] The applicant stated that, based on these results, LIVTENCITY™ is superior to conventional antiviral therapies in achieving and maintaining CMV viremia clearance and symptom control.

The applicant also claimed that the efficacy of LIVTENCITY™ is consistent across SOT types, as evidenced by an unpublished subgroup analysis by Avery et al.[170] which evaluated 211 SOT patients from the SOLSTICE trial for CMV clearance (LIVTENCITY™ vs. conventional) by transplant type, with the following results: heart: 42.9% (n=6/14) vs. 11.1% (n=1/9) (adjusted difference: 30.7% [95% CI, −1.72–63.15%]); lung: 47.5% (n=19/40) vs. 13.6% (n=3/22), adjusted difference: 38.2% [95% CI, 16.89–59.53%]; kidney: 59.5% (n=44/74) vs. 34.4% (n=11/32); adjusted difference: 26.7% [95% CI, 7.48–45.85%].

Finally, with regard to efficacy, the applicant stated that LIVTENCITY™ is active against refractory or resistant CMV infections and tolerable across doses. To support this claim, the applicant pointed to a randomized, dose-ranging, open-label, phase II study by Papanicolaou et al.,[171] in which HCT and SOT recipients with refractory or resistant CMV infections (n=120) were randomized 1:1:1 to twice-daily LIVTENCITY™ doses of 400 mg (n=40), 800 mg (n=40), or 1,200 mg (n=40) for up to 24 weeks. The primary efficacy endpoint was the proportion of patients with confirmed undetectable plasma CMV DNA within 6 weeks of treatment. About two-thirds (n=80/120) of the patients achieved undetectable plasma CMV DNA within 6 weeks of treatment among all doses [95% CI, 57–75%], and 70% of patients receiving 400 mg of LIVTENCITY™ twice daily [95% CI, 53–83]; 62% of patients receiving 800 mg twice daily [95% CI, 46–77%], and 68% of patients receiving 1,200 mg twice daily [95% CI, 51–81%] achieved the primary endpoint. About a third of patients experienced recurrent CMV infection while on LIVTENCITY™ (n=25) and 13 patients developed mutations conferring LIVTENCITY™ resistance.

To support the claim of decreased adverse effects, the applicant cited the results of two secondary endpoints from the SOLSTICE trial. Per the applicant, neutropenia and acute kidney injury are known, common adverse effects associated with valganciclovir/ganciclovir and foscarnet, respectively. The applicant noted that the rates of treatment-related neutropenia and acute kidney injury were both 1.7% (n=4/234), separately, in the LIVTENCITY™ treatment group. The applicant also noted that the rate of neutropenia was 25% (n=14/56) in the valganciclovir/ganciclovir group, and the rate of acute kidney injury was 19.1% (n=9/47) in the foscarnet group.[172] The applicant maintained that the rate of treatment-related neutropenia and acute kidney injury was lower in the LIVTENCITY™ group vs. conventional therapy group. The applicant asserted that, based on these results, LIVTENCITY™ has a lower incidence of treatment-related toxicities than existing therapies.

The applicant more specifically claimed that transplant patients treated with LIVTENCITY™ for CMV infection experienced a lower incidence of treatment-related neutropenia compared with valganciclovir. To support this claim, the applicant cited the primary safety endpoint from Maertens et al.,[173] a parallel-group, phase II study. In this open-label, LIVTENCITY™-blinded trial, 120 HCT or SOT recipients with CMV reactivation were randomly assigned to receive LIVTENCITY™ at a dose of 400 mg (n=40), 800 mg (n=40), or 1,200 mg (n=40) twice daily or the standard dose of valganciclovir for 12 weeks for preemptive treatment. The primary efficacy endpoint was the

[164] Failure to achieve >1 $\log_{10}$ decrease in CMV DNA after at least 14 days of anti-CMV treatment.

[165] At least 1 genetic mutation associated with resistance to ganciclovir/valganciclovir, foscarnet, and/or cidofovir.

[166] Avery RK, Alain S, Alexander B, et al. Maribavir for refractory cytomegalovirus infections with or without resistance post-transplant: results from a phase 3 randomized clinical trial (accepted manuscript). *Clin Infect Dis.* 2021; ciab988, *https://doi.org/10.1093/cid/ciab988.*

[167] Measured as CMV DNA level less than lower limit of quantification.

[168] Resolution or improvement in tissue-invasive CMV disease or syndrome for participants symptomatic at baseline or no new symptoms of tissue-invasive CMV disease or syndrome for participants asymptomatic at baseline.

[169] Avery RK, Alain S, Alexander B, et al. Maribavir for refractory cytomegalovirus infections with or without resistance post-transplant: results from a phase 3 randomized clinical trial (accepted manuscript). *Clin Infect Dis.* 2021; ciab988, *https://doi.org/10.1093/cid/ciab988.*

[170] Avery RK, Blumberg EA, Florescu D, et al. A randomized phase 3 open-label study of maribavir vs. investigator-assigned therapy for refractory/resistant cytomegalovirus infection in transplant recipients: subgroup analyses of efficacy by organ. in: *The 2021 American Transplant Congress;* 2021. Abstract LB 9.

[171] Papanicolaou GA, Silveira FP, Langston AA, et al. MBV for r/r CMV infections in HCT or SOT recipients: A randomized, dose-ranging, double-blind, phase 2 study. *Clin Infect Dis.* 2019;68(8):1255–1264. doi:10.1093/cid/ciy706.

[172] Avery R.K., Alain S., Alexander B., et al. Maribavir for refractory cytomegalovirus infections with or without resistance post-transplant: results from a phase 3 randomized clinical trial (accepted manuscript). *Clin Infect Dis.* 2021; ciab988, *https://doi.org/10.1093/cid/ciab988.*

[173] Maertens J., Cordonnier C., Jaksch P., et al. Maribavir for preemptive treatment of cytomegalovirus reactivation. *N. Engl J. Med.* 2019;381(12):1136–1147. doi:10.1056/NEJMoa1714656.

percentage of patients with a response to treatment, defined as confirmed undetectable CMV DNA in plasma, within 3 weeks and 6 weeks after the start of treatment. The primary safety endpoint was the incidence of adverse events that occurred or worsened during treatment. Specifically, the applicant cited the rate of treatment-emergent neutropenia in this study which was identified in 4% (n=5/118) of patients administered LIVTENCITY™ versus 15% (n=6/39) of patients administered valganciclovir through week 6. Similar results were found through week 12: 5% (n=6/118) vs. 18% (n=7/39). The statistical significance of the difference in treatment-emergent neutropenia between the two groups was not reported in the study.

Finally, the applicant stated that LIVTENCITY™ had a lower incidence of adverse events leading to discontinuation. To support this assertion, the applicant cited the rate of treatment-emergent adverse effects (TEAEs) leading to discontinuation from SOLSTICE, which was lower in the LIVTENCITY™ group (13.2% (n=31/324)) vs. the conventional group (31.9% (n=37/116)).[174]

In the proposed rule, we stated we had the following concerns regarding whether LIVTENCITY™ meets the substantial clinical improvement criterion. First, while the applicant provided data to demonstrate that the proportion of patients achieving CMV clearance at 8 weeks was higher among patients using LIVTENCITY™, there were similar rates of mortality and new-onset CMV between the 2 treatment groups in this trial: LIVTENCITY™ vs. comparator: 11% (n=27/235) vs. 6% (n=13/117) and 6% (n=14/235) vs. 6% (n=7/113), respectively.[175] We also noted that it is unclear whether the SOLSTICE study was sufficiently powered to detect a difference in CMV viremia clearance at week 16, one of the study's secondary endpoints.[176] We further noted that while the rate of TEAEs leading to discontinuation was lower in the LIVTENCITY™ group, the rate of overall TEAEs and serious TEAEs in the SOLSTICE trial was similar between the two treatment groups [LIVTENCITY™ vs. comparator: any TEAE: 97.4% (n=229/234) vs. 91.4% (n=106/116), serious TEAE: 38.5% vs. 37.1%].[177] Furthermore, we stated that we would appreciate additional information from the applicant regarding safeguards taken to minimize or prevent bias from the treating physician in choosing the conventional therapy for patients in the investigator-assigned therapy group of the phase III trial.

We invited public comments on whether LIVTENCITY™ meets the substantial clinical improvement criterion.

Comment: We received several comments in support of approving new technology add-on payments for LIVTENCITY™. The applicant reiterated four reasons LIVTENCITY™ meets the substantial clinical improvement criterion, including: (1) being a new treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; (2) more rapid resolution of infection/disease; (3) reduction in at least one clinically significant adverse event, and (4) decreased number of hospitalizations. The applicant also submitted comments in response to CMS' concerns regarding the substantial clinical improvement criterion.

With respect to the concern that there were similar rates of mortality and new-onset CMV between the two treatment groups in the SOLSTICE study, the applicant stated that the study was not sufficiently powered nor was it long enough in duration to detect a difference in these two endpoints. With respect to all-cause mortality, the applicant stated that 8 weeks is often the longest duration permissible due to toxicities associated with the IAT treatment group, and that the underlying medical history of the patients and the short study duration contributed to the similar rate of mortality. The applicant further explained that all-cause mortality rates were assessed based on the randomized treatment group, regardless of LIVTENCITY™ rescue treatment in the IAT group. With respect to new-onset CMV, the applicant stated that CMV treatment, either via secondary prophylaxis or treatment with LIVTENCITY™, was not allowed after 8 weeks which could explain the similar rates between the two groups. They also noted that a higher proportion of LIVTENCITY™ patients with new onset symptomatic CMV were primary responders to LIVTENCITY™ treatment versus the IAT patients. Furthermore, the study participants had a history of multiple past recurrences, increasing the likelihood of CMV recurrence. Finally, the applicant emphasized that clinically relevant recurrence is more clinically meaningful than overall recurrence.

Another commenter concurred with the applicant, stating that the SOLSTICE study design and imbalances in certain, therapy-independent baseline characteristics for the LIVTENCITY™ group (for example, presence of CMV disease) could make it difficult to identify true differences in all-cause mortality and new-onset CMV amongst LIVTENCITY™ and comparators.

The applicant also responded to CMS' concern that the SOLSTICE study was not sufficiently powered to detect difference in CMV viremia clearance at week 16, one of the study's secondary endpoints. The applicant noted that the study was powered to detect difference in CMV viremia at week 8, which was the primary endpoint of the study.

In response to CMS' concern that overall rate of TEAEs and serious TEAEs in the SOLSTICE trial was similar between the two treatment groups, the applicant stated that the similar rate of TEAEs was due to complexity of the patient population. They noted that the rate of TEAEs in the LIVTENCITY™ group was driven by mild dysgeusia. Similarly, a commenter stated that while the rate of any TEAEs was similar for LIVTENCITY™ versus IAT, patients in the LIVTENCITY™ group primarily experienced dysgeusia which did not result in treatment discontinuation, while patients in the IAT group experienced cytopenias and renal disorders that did lead to treatment discontinuation. The applicant also stated that the rate of TEAEs was not adjusted for drug exposure; drug exposure was longer in the LIVTENCITY™ group versus the IAT group due to toxicities in the IAT group. Finally, they noted that TEAEs leading to discontinuation was higher in the IAT group versus the LIVTENCITY™ group.

Another commenter stated, with respect to the same concern, that while the rates of any serious TEAEs were similar between the groups, the rate of treatment-related serious TEAEs was lower in the LIVTENCITY™ group versus IAT (5.1% vs. 14.7%, respectively), with the benefit persisting when taking into account discontinuation rates. The commenter cited this result in support of a finding that LIVTENCITY™ is a unique oral therapeutic option for CMV that does not share the same problematic adverse events of currently used off-label agents which the commenter stated often lead to treatment discontinuation and thus,

[174] Avery R.K., Alain S., Alexander B., et al. Maribavir for refractory cytomegalovirus infections with or without resistance post-transplant: results from a phase 3 randomized clinical trial (accepted manuscript). *Clin Infect Dis.* 2021; ciab988, *https://doi.org/10.1093/cid/ciab988.*

[175] Ibid.

[176] Ibid.

[177] Ibid.

suboptimal treatment of CMV infection and disease.

The applicant also responded to CMS' request for additional information on safeguards taken to minimize or prevent bias from the treating physician in choosing the conventional therapy for patients in the IAT group of the SOLSTICE study. The applicant noted that SOLSTICE was designed as an open-label study because the investigators had to individualize the selection of the effective comparator in medically complex patients with concomitant medications and adjust dosing of the IAT agents based on renal function. Thus, the applicant asserted that an open-label design was a safe and practical way to conduct the study. The applicant also noted that the primary endpoint of the study was assessed based on an objective laboratory endpoint at a fixed timepoint. They stated that multiple sensitivity analyses were conducted to address potential bias due to different rates of early treatment discontinuation and that the primary endpoint was evaluated in subgroups to establish treatment consistency and study generalizability. The results of these sensitivity analyses of the primary efficacy endpoint were consistent with the results of the primary efficacy analysis and the benefit of the technology was also consistent across key subpopulations.

Response: We thank the commenters for their input and appreciate the clarifications in response to our concerns regarding the similar rates of mortality and new-onset CMV between the two treatment groups, the insufficient power to detect a difference in CMV viremia clearance at week 16, and the similar rates of overall TEAEs and serious TEAEs in the SOLSTICE study. Based on the additional information received, we agree that LIVTENCITY™ represents a substantial clinical improvement over existing technologies because it provides a new treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, and significantly improves the proportion of patients achieving CMV viremia at 8 weeks and maintaining CMV clearance and symptom control at week 8 through week 16, as well as reduces adverse effects such as neutropenia and nephrotoxicity compared to available therapies.

After consideration of the public comments we received, we have determined that LIVTENCITY™ meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for LIVTENCITY™ for FY 2023. Cases involving the use of LIVTENCITY™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW0DX38 (Introduction of maribavir anti-infective into mouth and pharynx, external approach, new technology group 8), XW0G738 (Introduction of maribavir anti-infective into upper GI, via natural or artificial opening, new technology group 8), or XW0H738 (Introduction of maribavir anti-infective into lower GI, via natural or artificial opening, new technology group 8).

In its application, the applicant estimated that the cost of LIVTENCITY™ is $50,000 for an 8-week course of therapy. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of LIVTENCITY™ is $32,500 for FY 2023.

e. UPLIZNA® (Inebilizumab-Cdon)

HTI–DAC, the manufacturer under the distributor Horizon Therapeutics USA, Inc., submitted an application for new technology add-on payment for UPLIZNA® (inebilizumab-cdon) for FY 2023. Per the applicant, UPLIZNA® is the first FDA-approved anti-cluster of differentiation 19 (CD19) B-cell depleter for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin–4 (AQP4) antibody positive, for which 80% of all patients with NMOSD test positive.[178] According to the applicant, the goal of UPLIZNA® is to reduce the risk of relapse and disability progression. The applicant explained UPLIZNA® is a CD19+ B cell-directed humanized afucosylated immunoglobulin F1 (IgG1) monoclonal antibody. The applicant further explained that CD19 is a cell surface antigen expressed on a broad range of B lymphocytes. Per the applicant, UPLIZNA® is a B-cell depleter that binds specifically to CD19, allowing it to target an extended range of B-cells that play a role in NMOSD. The applicant stated that following cell surface binding to CD19+ B lymphocytes, UPLIZNA® causes antibody-dependent cellular cytolysis (ADCC), resulting in significant and robust B-cell depletion.

NMOSD is a rare, severe autoimmune disease of the central nervous system that causes damage to the optic nerve, spinal cord, and brain stem. NMOSD affects approximately 10,000–15,000 people in the United States, and the incidence rate may be up to 9 times higher for women than for men, with prevalence approximately 2- to 3-fold higher among Black and Asian populations.[179] According to the applicant, NMOSD is characterized by unpredictable, recurrent attacks of inflammation of the optic nerve (optic neuritis) and/or of the spinal cord (transverse myelitis), and may also affect regions of the brain. The applicant stated that attacks can be severe and result in life-altering permanent disability, such as blindness and paralysis, and that recurring attacks can have cumulative effects resulting in significant morbidity. According to the applicant, aquaporin-4 antibodies are highly specific to NMOSD and AQP4 is expressed on astrocytes throughout the central nervous system. Per the applicant, in NMOSD, AQP4 antibodies bind to AQP4, resulting in astrocyte cell death and inflammation. The applicant stated that a sub-population of B-lineage cells, CD19+ plasmablasts, produce AQP4 antibodies and that certain CD19+ B-cells are increased in the blood of AQP4-seropositive individuals with NMOSD, with the highest levels observed during an attack. According to the applicant, by depleting a wide range of B-cells that express CD19 (including plasmablasts and some plasma cells), UPLIZNA® reduces the risk of relapses or attacks that may lead to permanent disability in NMOSD patients.

With respect to the newness criterion, the applicant stated that UPLIZNA® was designated as a Breakthrough Therapy and received Orphan Drug designation on February 10, 2016 for the treatment of NMOSD.[180] Per the applicant, UPLIZNA® received FDA approval on June 11, 2020, for the treatment of NMOSD in adult patients who are AQP4 antibody positive (BLA #761142). The applicant stated that UPLIZNA® became commercially available on July 9, 2020, following FDA approval. According to the applicant, UPLIZNA® is administered as an intravenous infusion, and titrated to completion, over approximately 90 minutes under the close supervision of an experienced

[178] Wingerchuck, D. (2009, November 15). Neuromyelitis optica: Effect of gender. Journal of the Neurological Sciences. Retrieved October 6, 2021, from *https://pubmed.ncbi.nlm.nih.gov/19740485/*.

[179] Flanagan, E.P. et al. (2016, April 4). Epidemiology of aquaporin-4 autoimmunity and Neuromyelitis Optica Spectrum. Wiley Online Library. Retrieved October 6, 2021, from *https://onlinelibrary.wiley.com/doi/10.1002/ana.24617*.

[180] U.S. Food and Drug Administration website: *https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm*.

healthcare professional. The applicant stated that the recommended initial dose is a 300 mg intravenous infusion followed 2 weeks later by a second 300 mg intravenous infusion. The applicant also stated that subsequent doses, starting 6 months from the first infusion, consist of a single 300 mg intravenous infusion every 6 months.

According to the applicant, the following ICD–10–PCS procedure codes may be used to identify administration of UPLIZNA® in the inpatient setting, though they are not specific to UPLIZNA®: 3E033GC (Introduction of other therapeutic substance into the peripheral vein, percutaneous approach) or 3E043GC (Introduction of other therapeutic substance into central vein, percutaneous approach). Effective October 1, 2022, the following ICD–10–PCS procedure codes were created to uniquely describe the use of UPLIZNA®: XW03398 (Introduction of inebilizumab-cdon into peripheral vein, percutaneous approach, new technology group 8) and XW04398 (Introduction of inebilizumab-cdon into central vein, percutaneous approach, new technology group 8).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments. According to the applicant, the only approved treatments for NMOSD are UPLIZNA®, Soliris® (eculizumab), and ENSPRYNG™ (satralizumab). We note that ENSPRYNG™ and Soliris® previously submitted applications for new technology add-on payments. Please see discussion of ENSPRYNG™ in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45019 through 45028) and Soliris® in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58684 through 58689).

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that UPLIZNA® is the only treatment for NMOSD that targets B-cells and causes B-cell depletion. The applicant contrasted the mechanism of action of UPLIZNA® with those of Soliris® and ENSPRYNG™. Per the applicant, the mechanism of action of Soliris® is the inhibition of aquaporin-4-antibody induced terminal complement C5b–9 deposition.[181] The applicant explained that Soliris® specifically binds to complement protein C5, inhibiting its cleavage to C5a and C5b and preventing the generation of C5b–9. The applicant also stated that ENSPRYNG™ is a recombinant humanized anti-human interleukin–6 (IL–6) receptor monoclonal antibody. Per the applicant, the mechanism of action of ENSPRYNG™ involves the inhibition of IL–6-mediated signaling through binding to soluble and membrane-bound IL–6 receptors.[182] Thus, the applicant asserted that each of the three FDA approved treatments for NMOSD—UPLIZNA®, Soliris®, and ENSPRYNG™—bind to a different molecular target and have different mechanisms of action.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG when compared to an existing technology, the applicant stated that cases representing patients who may be eligible for treatment with UPLIZNA® map to MS–DRGs 058, 059, or 060 (Multiple Sclerosis and Cerebellar Ataxia with MCC, with CC, or without CC/MCC, respectively), which are the same MS–DRGs to which existing technologies may also be assigned.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant asserted that, while UPLIZNA® treats a patient population with the same type of disease (NMOSD) as Soliris® or ENSPRYNG™, it offers a treatment option for a subset of this patient population, which differentiates it from existing technologies. Per the applicant, UPLIZNA® has not been shown to carry an increased risk of meningitis and may be used in patient populations who are unvaccinated with the meningococcal vaccine and/or are not able to use prophylactic antibiotics. The applicant noted that while patients with NMOSD who are unvaccinated with the meningococcal vaccine can still receive other approved treatments for NMOSD, such as Soliris® or ENSPRYNG™, they need to have a risk reduction protocol instituted at the time of treatment and, in some cases, may require two weeks of prophylactic antibacterial treatment first.[183] [184]

In summary, the applicant maintained that UPLIZNA® is not substantially similar to other currently available therapies and/or technologies because it uses a new mechanism of action and treats a different subset of the patient population with NMOSD compared to an existing technology.

In the proposed rule, we questioned whether the subset of the patient population with NMOSD—specifically, patients who are unvaccinated with the meningococcal vaccine—is considered a new patient population since, as previously discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45021), ENSPRYNG™ is also not contraindicated in patients with unresolved serious *Neisseria meningitidis* infections, and therefore, may be a treatment option for patients with meningococcal disease as well as UPLIZNA®. Furthermore, as we previously stated in the FY 2022 IPPS/LTCH PPS final rule, individuals that are not vaccinated against *Neisseria meningitidis* are not considered a separate patient population because eligibility can be easily attained via a widely available vaccine (86 FR 45027). Additionally, we questioned whether the additional requirements for patients taking Soliris®—namely participation in a risk reduction protocol related to the associated risk of meningococcal infections, and prophylactic antibiotic treatment that may result in a 2-week delay for treatment—constitute a new patient population for technologies without those requirements.

We invited public comments on whether UPLIZNA® is substantially similar to existing technologies and whether UPLIZNA® meets the newness criterion.

Comment: The applicant submitted a public comment regarding the newness criterion. With respect to the first criterion to determine newness, whether a product uses the same or similar mechanism of action, the applicant reiterated its assertion that UPLIZNA® has a novel mechanism of action which satisfies the newness criterion. The applicant stated that UPLIZNA® is the first and only B-cell depleting monotherapy approved for neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin–4 antibody positive. The applicant explained that the mechanism of action of UPLIZNA® involves binding to CD19+ B-cells leading to antibody-dependent, cell-mediated B-cell depletion. As a result, the applicant

[181] U.S. Food and Drug Administration. (2019, June). Soliris Prescribing Information. Retrieved October 6, 2021, from *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125166s431lbl.pdf.*

[182] Genentech. (2020, August). ENSPRYNG Factsheet. Retrieved October 6, 2021, from *https://www.gene.com/download/pdf/genentech_enspryng_factsheet.pdf.*

[183] Soliris® prescribing details: *https://solirispro.com/pdf/Soliris_USPI.pdf.*

[184] ENSPRYNG™ prescribing information: *https://www.gene.com/download/pdf/enspryng_prescribing.pdf.*

stated UPLIZNA® reduces the damage caused to the optic nerve, spinal cord, and brain by NMOSD attacks, thus reducing cumulative damage and rates of disability.

With respect to the third criterion to determine newness and our concern that patients who are unvaccinated with the meningococcal vaccine may not represent a new patient population for NMOSD, the applicant stated that in small populations such as those with rare diseases, special considerations such as vaccination status, prior therapies, drug interactions, or contraindications are important as certain nuances related to a particular treatment within these small populations can be uncovered, and providers must often choose one therapy over another due to specific patient attributes and health histories.

Response: We appreciate the applicant's input and agree that UPLIZNA® has a unique mechanism of action when compared to existing technologies for treating NMOSD, as UPLIZNA® is the only CD19+ B-cell depleting monotherapy approved for NMOSD in adult patients who are anti-aquaporin–4 antibody positive, compared to Soliris® which specifically binds to complement protein C5, and ENSPRYNG™ which binds to soluble and membrane-bound IL–6 receptors. However, we continue to believe that UPLIZNA® does not represent a treatment option for a new patient population. We stated in the FY 2022 IPPS/LTCH PPS final rule that individuals who are not vaccinated against *Neisseria meningitidis* are not considered a separate patient population because eligibility can easily be attained via a widely available vaccine (86 FR 45027). In addition, ENSPRYNG™, another approved medication for the treatment of NMOSD, is also not contraindicated in patients with unresolved serious *Neisseria meningitidis* infections and therefore, may be a treatment option for patients with meningococcal disease along with UPLIZNA®.

Based on the comments received and the information submitted as part of the FY 2023 new technology add-on payment application for UPLIZNA®, as discussed in the proposed rule (87 FR 28303 through 28304) and in this final rule, we believe that UPLIZNA® has a unique mechanism of action and is not substantially similar to existing treatment options for NMOSD. While the applicant stated that it became commercially available on July 9, 2020, we believe that the beginning of the newness period for UPLIZNA® would be June 11, 2020, which is the date that UPLIZNA® received FDA marketing authorization, as the applicant did not provide documentation of a delay in commercial availability.

With respect to the cost criterion, the applicant presented the following analysis. The applicant searched the FY 2019 Medicare Provider Analysis and Review (MedPAR) Hospital Limited Data Set (LDS) for cases with ICD–10–CM diagnosis code G36.0 for Neuromyelitis optica [Devic] (NMOSD) coded in the first diagnosis position. The applicant determined that cases representing patients who may be eligible for treatment with UPLIZNA® would map to MS–DRGs 058, 059, or 060 (Multiple Sclerosis and Cerebellar Ataxia with MCC, with CC, or without CC/MCC, respectively).

The applicant determined a case count of 257 after imputing a value of 11 for MS–DRGs with a case volume under 11. The applicant then removed 100% of the drug charges to estimate the potential decrease in costs due to the use of UPLIZNA®. The applicant noted that, although use of UPLIZNA® would replace current drug charges for therapies such as azathioprine, methotrexate, and rituximab, it is not possible to differentiate between drug costs on MedPAR claims, and so it removed all drug charges to be conservative. The applicant then standardized the charges and applied a 4-year inflation factor of 1.281834, or 28.1834%, based on the inflation factor used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542). The applicant added charges for the new technology by dividing the estimated cost of UPLIZNA® by the national average CCR for drugs which is 0.187, from the FY 2022 IPPS/LTCH PPS final rule (86 FR 44966).

The applicant calculated a final inflated average case-weighted standardized charge per case of $764,547, which exceeded the average case-weighted threshold amount of $48,165. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that UPLIZNA® meets the cost criterion.

We invited public comments on whether UPLIZNA® meets the cost criterion.

We did not receive any comments on whether UPLIZNA® meets the cost criterion. Based on the information submitted by the applicant as part of its FY 2023 new technology add-on payment application for UPLIZNA®, as discussed in the proposed rule (87 FR 28304) and previously summarized, the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, UPLIZNA® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant made two assertions. First, the applicant asserted that UPLIZNA® offers a treatment option for a patient population that is ineligible for currently available treatments. Specifically, the applicant asserted that UPLIZNA® is a new treatment option for patients who carry an increased risk of meningitis, patients following treatments with more frequent and burdensome dosing schedules, and patient populations more likely to be impacted by health disparities. Finally, the applicant asserted that UPLIZNA® significantly improves clinical outcomes relative to currently available technologies because it reduced the risk of NMOSD attacks and disability progression among patients with NMOSD when compared to placebo in the N–MOmentum trial, which the applicant asserted is the largest NMOSD study conducted.[185]

With respect to the applicant's assertion that UPLIZNA® is a substantial clinical improvement over existing technologies because it represents a new treatment option for a patient population ineligible for currently available treatments, the applicant stated that UPLIZNA® may be used in patient populations who are unvaccinated with the meningococcal vaccine and/or are not able to use prophylactic antibiotics because UPLIZNA® has not been shown to carry an increased risk of meningitis, as compared with Soliris®.

To support this claim, the applicant cited an article from the CDC explaining that patients taking complement inhibitors, such as Soliris®, are at an increased risk for meningococcal disease [186] and referenced the CDC's recommendation that patients receive the meningococcal vaccination prior to initiating treatment with a complement inhibitor. The applicant also cited a

[185] Marignier, R. et al., (2021, March 26). Disability Outcomes in the N–MOmentum Trial of Inebilizumab in Neuromyelitis Optica Spectrum Disorder. Neurology® neuroimmunology & neuroinflammation. Retrieved October 6, 2021, from *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8054974/*.

[186] Centers for Disease Control and Prevention. (2019, May 31). *Taking complement inhibitors increases risk for meningococcal disease*/CDC. Centers for Disease Control and Prevention. Retrieved October 1, 2021, from *https://www.cdc.gov/meningococcal/about/soliris-patients.html.*

study by McNamara et al.[187] that identified 16 cases in the U.S. between 2008 and 2016 of patients who were taking Soliris® who had meningococcal disease despite having received at least 1 dose of meningococcal vaccine before disease onset. Referring to the same article by McNamara et al., the applicant stated that some healthcare providers recommend prophylactic antibiotics even for vaccinated patients during treatment with Soliris®, exposing them to long-term antibiotic use, which carries the risk of developing antimicrobial resistance.

Furthermore, the applicant claimed that UPLIZNA® represents a new treatment option for patients following treatments with more frequent and burdensome dosing schedules than UPLIZNA®. Per the applicant, the dosing schedule for UPLIZNA® consists of 2 initial doses delivered 2 weeks apart, followed by 1 dose every 6 months after that.[188] In comparison, based on the FDA prescribing information for Soliris®, the applicant asserted that UPLIZNA®'s 6-month dosing regimen is less frequent than that of Soliris®, and, therefore, is less burdensome to follow.[189] The applicant asserted the dosing schedule for UPLIZNA® is more amenable to NMOSD patients for whom more frequent intravenous infusions may be burdensome and stated that its characteristics as a treatment regimen, compared to Soliris™, may help to improve medication adherence and decrease likelihood of relapse and hospitalization relative to placebo. To further demonstrate that UPLIZNA® may help to improve long-term patient adherence, compared to Soliris™, the applicant provided a review by Vlasnik et al.[190] noting that medication regimen complexity is one factor that can negatively affect adherence. The applicant emphasized that, for NMOSD, medication adherence to maintain immune suppression is essential for reducing the risk of attacks, which can lead to hospitalization, vision loss and paralysis. Finally, the applicant stated that UPLIZNA® poses less of a barrier for patient access, as it does not require patients or providers to participate in FDA's Risk Evaluation and Mitigation Strategy (REMS) program, or receive additional counselling regarding the program, as required by Soliris®.[191]

To support its claim that UPLIZNA® is a new treatment option for populations that are more likely to be impacted by health disparities, the applicant noted UPLIZNA®'s durable efficacy and favorable safety profile among African Americans with NMOSD. To support this claim, the applicant cited the safety results published by Cree et al.[192] from both a randomized control period (RCP) and an open label period (OLP) of the N–MOmentum trial. The RCP phase of N–Momentum was a multicenter, double-blind, 2/3 study conducted at 99 outpatient specialty clinics or hospitals in 25 countries that lasted up to 197 days. The primary endpoint was time to onset of an NMOSD attack, as determined by the investigator and adjudication committee. Eligible participants were randomized in a 3:1 ratio to receive either 300 mg intravenous UPLIZNA® (n=174) or a saline placebo (n=56) on days 1 and 15. Participants continued through the RCP for up to 28 weeks unless they had a confirmed NMOSD attack, at which point they could choose to continue in the OLP phase of the trial. The OLP included eligible adult participants (n=230) who had had at least 1 NMOSD attack in the year before screening or at least 2 attacks requiring rescue therapy in the 2 years before screening. During the OLP, all patients received UPLIZNA® for at least 2 years. As recommended by an independent committee, enrollment in the RCP phase stopped prior to study completion due to the early findings where 21 of 174 participants (12%) receiving UPLIZNA® had an attack as compared with 22 of the 56 placebo recipients (39%). Marignier et al. (2021) assessed treatment effects in N–MOmentum by measuring score worsening of the Expanded Disability Status Scale (EDSS) and modified Rankin Scale (mRS) scores.[193] EDSS scores were measured at baseline, then at RCP study weeks 12 and 28, and every 3 months during the OLP, and within 5 days of a potential attack. mRS scores were measured at baseline, and at weeks 4, 8, 12, 16, 22, and 28 of the RCP. The Marignier results from the N–MOmentum study found the annualized attack rate for African Americans was lower at 0.06 compared to an annualized attack rate of 0.09 in the overall group exposed to UPLIZNA®. The applicant stated that among the 19 African American participants who received UPLIZNA® or placebo during the RCP and/or OLP of the N–MOmentum trial, three had attacks 18, 29, and 104 days after their first UPLIZNA® dose. The summary of baseline demographics and characteristics of the intent-to-treat population notes that there were 14 African American participants who received UPLIZNA® and 5 who received the placebo.[194]

With respect to its claim that UPLIZNA® significantly improves clinical outcomes relative to previously available treatment options, the applicant stated that patients taking UPLIZNA® had a reduced risk of NMOSD attacks and disability progression when compared to placebo in the N–MOmentum trial. The applicant again referenced the results of the N–MOmentum trial reported by Cree et al., where 21 (12%) of the 174 participants receiving UPLIZNA® had an attack by the time enrollment ended versus 22 (39%) of the 56 participants receiving placebo (hazard ratio (HR) 0·272 [95% CI 0·150–0·496]; p<0·0001). The applicant also referred to the N–MOmentum results from the OLP and asserted that they show long-term treatment with UPLIZNA® provided a sustained reduction in NMOSD attack risk, MRI lesions, and NMOSD-related hospitalizations regardless of treatment provided during the RCP. The applicant

[187] McNamara, L. et al. (2017, July 7). High Risk for Invasive Meningococcal Disease Among Patients Receiving Eculizumab (Soliris) Despite Receipt of Meningococcal Vaccine. Retrieved October 6, 2021, from *https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6627e1.pdf.*

[188] U.S. Food and Drug Administration. (2007, March). Highlights of prescribing information administration. Retrieved October 6, 2021, from *https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/125166lbl.pdf.*

[189] U.S. Food and Drug Administration. Alexion briefing information for the November 18, 2014, meeting of the Drug Safety and Risk Management Advisory Committee. *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/drug-safety-and-risk-management-advisory-committee.*

[190] Vlasnik, J. J., Aliotta, S. L., & DeLor, B. (2005, April 7). Medication adherence: Factors influencing compliance with prescribed medication plans. The Case Manager. Retrieved October 6, 2021, from *https://www.sciencedirect.com/science/article/abs/pii/S1061925905000263?via%3Dihub.*

[191] Alexion Pharmaceutical, Inc. (2020). Soliris REMS. Retrieved October 6, 2021, from *https://solirisrems.com/.*

[192] Cree BAC, Bennett JL, Kim HJ, Weinshenker BG, Pittock SJ, Wingerchuk DM, Fujihara K, Paul F, Cutter GR, Marignier R, Green AJ, Aktas O, Hartung HP, Lublin FD, Drappa J, Barron G, Madani S, Ratchford JN, She D, Cimbora D, Katz E; N–MOmentum study investigators. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N–MOmentum): a double-blind, randomised placebo-controlled phase 2/3 trial. Lancet. 2019 Oct 12;394(10206):1352–1363. doi: 10.1016/S0140–6736(19)31817–3. Epub 2019 Sep 5. PMID: 31495497.

[193] Marignier R, Bennett JL, Kim HJ, Weinshenker BG, Pittock SJ, Wingerchuk D, Fujihara K, Paul F, Cutter GR, Green AJ, Aktas O, Hartung HP, Lublin FD, Williams IM, Drappa J, She D, Cimbora D, Rees W, Smith M, Ratchford JN, Katz E, Cree BAC; N–MOmentum Study Investigators. Disability Outcomes in the N–MOmentum Trial of Inebilizumab in Neuromyelitis Optica Spectrum Disorder. Neurol Neuroimmunol Neuroinflamm. 2021 Mar 26;8(3):e978. doi: 10.1212/NXI.0000000000000978. PMID: 33771837; PMCID: PMC8054974.

[194] Ibid.

referenced the disability data published by Marignier et al.[195] from the results of the N–MOmentum trial on the use of UPLIZNA® and asserted that they showed favorable results among patients with NMOSD when compared to placebo. Specifically, Marignier et al. assessed the treatment effects of UPLIZNA® in comparison with placebo by using a worsening score of the Expanded Disability Status Scale (EDSS) to measure confirmed disability progression (CDP). The applicant asserted that the results show UPLIZNA® reduced the risk of 3-month CDP compared with placebo (HR: 0.375; 95% CI: 0.148–0.952; p=0.0390). The applicant also stated that UPLIZNA® showed a significantly lower risk of relapse among patients with NMOSD when compared to placebo. The applicant cited results from Pittock et al.,[196] a randomized, double-blind, time-to-event trial in which 143 adult subjects were randomly assigned to receive either UPLIZNA® or placebo weekly and continued use of an immunosuppressive therapy, as needed. The primary endpoint was the first adjudicated relapse, while secondary endpoints included the adjudicated annualized relapse rate. Pittock et al. reported that adjudicated relapses occurred in 3 of 96 patients (3%) in the UPLIZNA® group and 20 of 47 (43%) in the placebo group (hazard ratio 0.06; 95% confidence interval [CI], 0.02 to 0.20; P<0.001). The adjudicated annualized relapse rate was 0.02 in the eculizumab group and 0.35 in the placebo group (rate ratio, 0.04; 95% CI, 0.01 to 0.15; P<0.001). Referring to the results from the Pittock et al. study, the applicant asserted that UPLIZNA® showed a consistent effect in reducing the risk of attack compared to placebo, regardless of baseline disability status, attack history, or disease duration.[197]

In the proposed rule, we stated we had the following concerns regarding whether UPLIZNA® meets the substantial clinical improvement criterion. First, we noted that while the applicant provided data comparing UPLIZNA® to placebo, we did not receive any data to demonstrate improved outcomes over existing FDA approved treatments. We stated that additional information comparing outcomes such as relapse rate, risk of relapse, and disability progression for patients receiving UPLIZNA® versus other currently available treatments would help inform our assessment of whether UPLIZNA® demonstrates a substantial clinical improvement over existing technologies. Second, while the applicant asserted that UPLIZNA® represents a new treatment option for patients who are unvaccinated with the meningococcal vaccine, similar to the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45021) in response to a similar assertion with respect to ENSPRYNG™, we noted that ENSPRYNG® is also not contraindicated in patients with unresolved serious *Neisseria meningitidis* infection and therefore may also be a treatment option for patients with meningococcal disease. We further noted that the use of ENSPRYNG™ to treat patients with NMOSD does not require a meningococcal vaccination. We noted that the applicant sought to support its claim that UPLIZNA® represents a new treatment option for patients who are unvaccinated against *Neisseria meningitidis* through the inference that Soliris® has a high risk of causing meningitis; however, as stated in the proposed rule, we had concerns about the applicant's claim because *Neisseria meningitidis* may easily be mitigated through the use of a common vaccine or antimicrobials. As discussed in the FY 2022 IPPS/LTCH PPS final rule in response to similar claims with respect to ENSPRYNG®, and as noted previously, individuals that are not vaccinated against *Neisseria mengitidis* are not considered a separate patient population because eligibility can be easily attained via a widely available vaccine and are also able to receive treatment with UPLIZNA® which does not require a vaccine (86 FR 45027).

With regard to the applicant's claim that UPLIZNA® is a new treatment option for patients following treatments with more frequent dosing schedules, we stated in the proposed rule that we are unsure whether these patients may be considered as a separate patient population ineligible for currently available treatments. For example, although the applicant compared the UPLIZNA® dosing regimen against Soliris®, it did not provide a similar comparison against ENSPRYNG™, which—similar to UPLIZNA®—does not require frequent intravenous infusions or participation in the FDA REMS program (see 86 FR 45020). Therefore, we stated that it is unclear whether UPLIZNA® provides a treatment option for a separate patient population that is ineligible for currently available treatments, when there are other available treatments, like ENSPRYNG™, without the limitations that the applicant described with respect to Soliris®. In addition, while the applicant stated that UPLIZNA's® dosing regimen may help to improve long-term patient medication adherence and decrease the likelihood of relapse and hospitalization, we questioned the strength of the correlation between UPLIZNA's® dosing regimen and these outcomes. We stated our interest in additional information on the efficacy results of UPLIZNA® among African Americans with NMOSD, as cited by the applicant, as we understand that NMOSD disproportionately affects African American and Asian populations at rates approximately 2- to 3-fold higher than their Caucasian counterparts.[198] Specifically, we questioned whether the retrospective analysis of the results from the N–MOmentum trial on the annualized attack rate for African Americans (0.06 compared with 0.09 in the overall group) is generalizable to larger populations because the study included low numbers of participants. Of the 20 African American participants randomized in N-Momentum, 19 were AQP4 antibody positive and 1 was AQP4 antibody negative. As a result, of the 19 participants, 14 received UPLIZNA®, and only 5 received placebo.[199] [200] We further noted that the applicant did not provide comparative data on the efficacy of UPLIZNA®,

[195] Marignier R, Bennett JL, Kim HJ, Weinshenker BG, Pittock SJ, Wingerchuk D, Fujihara K, Paul F, Cutter GR, Green AJ, Aktas O, Hartung HP, Lublin FD, Williams IM, Drappa J, She D, Cimbora D, Rees W, Smith M, Ratchford JN, Katz E, Cree BAC; N–MOmentum Study Investigators. Disability Outcomes in the N–MOmentum Trial of Inebilizumab in Neuromyelitis Optica Spectrum Disorder. Neurol Neuroimmunol Neuroinflamm. 2021 Mar 26;8(3): e978. doi: 10.1212/NXI.0000000000000978. PMID: 33771837; PMCID: PMC8054974.

[196] Pittock SJ, Berthele A, Fujihara K, Kim HJ, Levy M, Palace J, Nakashima I, Terzi M, Totolyan N, Viswanathan S, Wang KC, Pace A, Fujita KP, Armstrong R, Wingerchuk DM. Eculizumab in Aquaporin–4-Positive Neuromyelitis Optica Spectrum Disorder. N Engl J Med. 2019 Aug 15;381(7):614–625. doi: 10.1056/NEJMoa1900866. Epub 2019 May 3. PMID: 31050279.

[197] Ibid.

[198] Flanagan, E.P. et al. (2016, April 4). Epidemiology of aquaporin-4 autoimmunity and Neuromyelitis Optica Spectrum. Wiley Online Library. Retrieved October 6, 2021, from *https://onlinelibrary.wiley.com/doi/10.1002/ana.24617*.

[199] Bernitsas, E., Cimbora, D., Dinh, Q., She, D., Katz, E. Safety and Efficacy of Inebilizumab in African Americans with Neuromyelitis Optica Spectrum Disorder. Poster presentation at the 15th World Congress on Controversies in Neurology (CONy Virtual). September 23–26, 2021.

[200] Cree BAC, Bennett JL, Kim HJ, Weinshenker BG, Pittock SJ, Wingerchuk DM, Fujihara K, Paul F, Cutter GR, Marignier R, Green AJ, Aktas O, Hartung HP, Lublin FD, Drappa J, Barron G, Madani S, Ratchford JN, She D, Cimbora D, Katz E; N–MOmentum study investigators. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N–MOmentum): a double-blind, randomised placebo-controlled phase 2/3 trial. Lancet. 2019 Oct 12;394(10206):1352–1363. doi: 10.1016/S0140–6736(19)31817–3. Epub 2019 Sep 5. PMID: 31495497.

Soliris®, and ENSPRYNG™ in these populations.

We invited public comments on whether UPLIZNA® meets the substantial clinical improvement criterion.

Comment: We received several comments in support of new technology add-on payments for UPLIZNA®, including one from the applicant, in response to CMS' concerns in the proposed rule. With respect to the concern regarding the lack of data comparing UPLIZNA® to existing FDA-approved treatments, the applicant stated that conducting head-to-head trials is often not possible when studying rare diseases due to the small patient populations and potential delays if trials for the same indication are running simultaneously. The applicant noted that the timing and availability of Soliris® and ENSPRYNG™ (approved by FDA on June 27, 2019 and August 17, 2020, respectively) did not allow for comparative trials, as there were no approved medications for the treatment of NMOSD for the entirety of the N–MOmentum study. The applicant stated that CMS has granted new technology add-on payments in situations where comparative head-to-head trials were not available, referencing two technologies without comparative clinical data that were granted new technology add-on payments in FY 2019 and FY 2022, as well as two additional examples from FY 2022 that were both FDA-approved based on the results of single-arm clinical trials. We note that the applicant did not identify the specific technologies. The applicant stated that, because these products were granted new technology add-on payments without direct comparative data with their respective clinical competitors, that substantial clinical improvement can be ascertained through product attributes and randomized clinical trial outcomes in the absence of direct, comparative head-to-head trials.

With respect to the concern regarding the lack of data demonstrating improved outcomes over existing FDA approved treatments, the applicant noted that N–MOmentum is the largest-ever clinical trial conducted in patients with NMOSD, the results of which showed that patients taking UPLIZNA® experienced fewer relapses and fewer hospitalizations than patients on placebo. The applicant stated that compared with placebo, patients treated with UPLIZNA® had a reduced risk of 3-month EDSS-confirmed disability progression (CDP). The applicant also noted that although disability outcomes data cannot be compared across therapies, other therapies' disability data were studied using different endpoints as secondary measures and/or were not reported because of lack of statistical significance. The applicant referred to the PREVENT trial for Soliris®, which studied EDSS and mRS as secondary outcome measures up to 211 weeks and noted that there was no significant difference in disability progression between the Soliris® groups and placebo. The applicant also referred to the SakuraStar and SakuraSky trials for ENSPRYNG and noted that no significant effect on disability was observed. In contrast, the applicant stated that UPLIZNA® showed a consistent effect in reducing the risk of disability worsening compared to placebo, regardless of baseline disability status, attack history, or disease duration. The applicant asserted that despite head-to-head studies not being possible at the time registrational trials were conducted, the data and efficacy and clinical efficiency attributes of UPLIZNA® present an improvement for patients over other therapies.

In response to CMS' feedback regarding the comparison of dosing and long-term adherence to other available treatments for NMOSD, the applicant confirmed it had provided details of dosing for Soliris® in its application and included dosing details for ENSPRYNG™ in its comments, noting that ENSPRYNG™ requires more frequent administration than UPLIZNA®. The applicant referenced long-term adherence data showing that UPLIZNA® adherence was approximately 85% after two years. The applicant stated that the improved medication adherence data from analogue disease states suggest that twice yearly dosing, as with UPLIZNA®, is associated with improved adherence over other regimens. The applicant also stated that the data suggest that adherence and persistence to therapy may lead to improved clinical outcomes.

In addition, the applicant extrapolated results from a retrospective claims analysis looking at the use of MS disease-modifying therapies (DMTs) that concluded that a twice-yearly dosing schedule achieved superior adherence and persistence at 12, 18, and 24 months versus other dosing regimens or routes of administration. Other commenters also mentioned the convenient dosing schedule of UPLIZNA®, which potentially simplifies the lives of NMOSD patients and thereby improves compliance, which they noted is critical for the prevention of disease relapse and for ensuring good patient outcomes.

The applicant noted that persistence and adherence to a therapy such as UPLIZNA® are important to achieving positive clinical outcomes, and reiterated that studies have shown that relapses can lead to hospitalizations, long-term disability, and permanent harm to the patient. According to a commenter, administration of UPLIZNA® in the hospital setting, immediately after diagnosis and acute treatment of the relapse can be life saving for the patient, as early treatment leads to better outcomes and reduces relapse rate and subsequent disability. Commenters emphasized the potential for permanent damage related to relapses of NMOSD and therefore the importance of timely treatment to prevent relapse.

The applicant also responded to CMS' question regarding the generalizability of the retrospective analysis of the efficacy results of UPLIZNA® among Black/African American patients with NMOSD, which the applicant provided to support its claim that UPLIZNA® is a new treatment option for populations that are more likely to be impacted by health disparities. NMOSD disproportionately affects Black/African American and Asian populations at rates approximately 2-to 3-fold higher than Caucasians. As noted in its application, the applicant stated that the annualized attack rates for Black/African American participants observed in the N–MOmentum study were promising, despite the relatively low number of participants in the study. The applicant noted that the FDA Statistical Review of UPLIZNA® confirmed that the applicant could report subgroup analyses based on sex, race, age, and region and these data suggest that UPLIZNA® is at least as effective in the Black/African American subpopulation as it is in the general patient population. The applicant noted the difficulty of enrolling large numbers of patients in studies for rare conditions, and stated that subgroup data provided can still represent important considerations in identifying a benefit in populations that face disproportionately higher rates of NMOSD. As is often the case with rare diseases such as NMOSD, relatively small numbers of participants result in small subpopulations; however, the applicant noted, interpreting results in small subgroups must be done cautiously.

Response: We thank the commenters for their input. After further review, we continue to have concerns as to whether UPLIZNA® meets the substantial clinical improvement criterion to be approved for new technology add-on payments. We agree with the

commenters that timely treatment for relapse prevention in NMOSD is important. However, it is unclear whether UPLIZNA® leads to improved relapse prevention, or other improved outcomes, as compared to other available treatments for NMOSD. We note that the applicant did not provide data comparing outcomes such as time to first relapse and number of relapses with Soliris® or UPLIZNA®. We further note that the applicant stated that, of the available therapies, only UPLIZNA® demonstrated a statistically significant effect on disability progression compared to placebo in its clinical trial. However, as the applicant noted, there were differences between the trials, including size of the trials and disability endpoints assessed. We believe this makes it difficult to demonstrate superior effect on disability progression, especially without a comparison of relapse rates, with which disability is associated. We also note that time-to-first-relapse is one endpoint that was consistent across all three trials, and that the results of a meta analysis comparing published efficacy outcomes for Soliris®, UPLIZNA®, and ENSPRYNG™ showed that Soliris® demonstrated greater efficacy in prolonging time-to-relapse compared to UPLIZNA® and ENSPRYNGTM.[201] While we agree with the applicant that substantial clinical improvement can be determined without head-to-head trials, we note that we evaluate every application on its own data and merits to determine whether it meets the new technology add-on payment criterion for substantial clinical improvement, and we consider variations in the currently available technologies that an applicant technology is compared against for the purposes of determining whether the technology represents a substantial clinical improvement over existing technologies. We further note that it is unclear which technologies the applicant is referring to in stating that CMS has previously approved new technology add-on payments for technologies without a demonstration of comparative outcomes.

Furthermore, with regard to improved adherence, while the applicant provided information regarding UPLIZNA® adherence, it did not compare these values to adherence for other therapies and therefore this information does not support a finding of substantial clinical improvement. Lastly, the retrospective claims analysis the applicant provided to support a correlation between long-term medication adherence and decreased relapse and hospitalization assessed the adherence and persistence of multiple sclerosis patients treated with a drug that had the same dosing regimen as UPLIZNA®—but not NMOSD patients treated with UPLIZNA®.

After review of the information submitted by the applicant as part of its FY 2023 new technology add-on payment application for UPLIZNA® and consideration of the comments received, we are unable to determine that UPLIZNA® meets the substantial clinical improvement criterion for the reasons discussed in the proposed rule and in this final rule, and therefore we are not approving new technology add-on payments for UPLIZNA® for FY 2023.

7. FY 2023 Applications for New Technology Add-On Payments (Alternative Pathways)

As discussed previously, beginning with applications for FY 2021, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation may qualify for the new technology add-on payment under an alternative pathway. Additionally, beginning with FY 2021, under the regulations at § 412.87(d), a medical product that is designated by FDA as a QIDP and has received marketing authorization for the indication covered by the QIDP designation, and, beginning with FY 2022, a medical product that is a new medical product approved under FDA's LPAD and used for the indication approved under the LPAD pathway, may also qualify for the new technology add-on payment under an alternative pathway. Under an alternative pathway, a technology will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still be within the 2–3 year newness period to be considered ''new,'' and must also still meet the cost criterion. We refer readers to section II.H.8. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and section II.F.6 of preamble of the FY 2021 IPPS/LTCH PPS final rule (85 FR 58715 through 58733) for further discussion of the alternative new technology add-on payment pathways for these technologies.

We note, section 1886(d)(5)(K)(ii)(II) of the Act provides for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology. Our regulations in § 412.87(c)(2) for breakthrough devices and § 412.87(d)(2) for certain antimicrobial products state that a medical device/product that meets the condition in paragraph (c)(1) or (d)(1) of § 412.87 will be considered new for not less than 2 years and not more than 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Act) assigned to the new technology (depending on when a new code is assigned and data on the new technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology, the medical technology will no longer be considered ''new'' under the criterion of this section.

We received 19 applications for new technology add-on payments for FY 2023 under the new technology add-on payment alternative pathways. Six applicants withdrew applications prior to the issuance of the proposed rule. Subsequently, five applicants withdrew their respective applications for LigaPASS 2.0 PJK Prevention System, Magnus Neuromodulation System with SAINT Technology, the Precision TAVI™ Coronary Module, the TOPS™ System, and the VITARIA® System prior to the issuance of this final rule. Two applicants, Phagenesis Ltd. (the applicant for Phagenyx® System) and Neuro Event Labs, Inc. (the applicant for the Nelli® Seizure Monitoring System), did not meet the July 1 deadline for FDA approval or clearance of the technology and, therefore, the technologies are not eligible for consideration for new technology add-on payments for FY 2023. A discussion of the remaining 6 applications is presented in this final rule, including 5 technologies that have received a Breakthrough Device designation from FDA and 1 that was designated as a QIDP by FDA.

In accordance with the regulations under § 412.87(e)(2), applicants for new technology add-on payments, including Breakthrough Devices, must have FDA marketing authorization by July 1 of the

[201] Wingerchuck, et al. Indirect comparison analysis of FDA-approved treatment options for adults with aquaporin–4 immunoglobulin G-positive neuromyelitis optica spectrum disorder.

year prior to the beginning of the fiscal year for which the application is being considered. Under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742), we revised the regulations at § 412.87(e) by adding a new paragraph (e)(3) which provides for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for a complete discussion of this policy (85 FR 58737 through 58742).

As we did in the FY 2022 IPPS/LTCH PPS proposed rule, for applications under the alternative new technology add-on payment pathway, in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to approve or disapprove each of these six applications for FY 2023 new technology add-on payments. Therefore, in this section of the preamble of this final rule, we provide background information on each of the remaining six alternative pathway applications and our determinations as to whether or not each technology is eligible for new technology add-on payments for FY 2023. Consistent with our standard approach, we are not including in this final rule the description and discussion of applications that were withdrawn or that are ineligible for consideration for FY 2023 due to not meeting the July 1 deadline, described previously, which were included in the FY 2023 IPPS/LTCH PPS proposed rule. We are also not summarizing nor responding to public comments received regarding these withdrawn or ineligible applications in this final rule.

a. Alternative Pathway for Breakthrough Devices

(1) CERAMENT® G

BONESUPPORT AB submitted an application for new technology-add on payments for CERAMENT® G for FY 2023. Per the applicant, CERAMENT® G is an injectable bone-void filler made of calcium sulfate, hydroxyapatite, and gentamicin sulfate indicated for the surgical treatment of osteomyelitis. Per the applicant, this bone graft substitute fills gaps resulting from debridement of infected bone and prevents colonization of sensitive bacteria, promoting bone healing in two ways. The applicant stated that the primary mode of action is for CERAMENT® G to act as a resorbable ceramic bone-void filler intended to fill gaps and voids in the skeleton system created when infected bone is debrided. The applicant also stated that the secondary mode of action is to prevent the colonization of gentamicin-sensitive microorganisms in order to protect bone healing. Per the applicant, CERAMENT® G may eliminate the need to harvest autologous bone, avoiding pain and infection at the donor site. We note that BONESUPPORT Inc. previously submitted an application for new technology add-on payments for CERAMENT® G for FY 2022, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25368 through 25373) but the technology did not meet the deadline of July 1, 2021, for FDA approval or clearance of the technology and, therefore, was not eligible for consideration for new technology add-on payments for FY 2022 (86 FR 45126 through 45127).

According to the applicant, CERAMENT® G is designated as a Breakthrough Device for use as a bone-void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis. The technology received FDA De Novo marketing authorization on May 17, 2022 with an indication for use as a bone void filler in skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis in defects in the extremities. The applicant applied for and received a unique ICD–10–PCS procedure code to identify cases involving the administration of CERAMENT® G in 2021. Effective October 1, 2021, CERAMENT® G administration can be identified by ICD–10–PCS procedure code XW0V0P7 (Introduction of antibiotic eluting bone void filler into bones, open approach, new technology group 7), which is unique to CERAMENT® G administration. The applicant stated that the following existing ICD–10–CM codes for osteomyelitis appropriately describe the proposed indication for which the device received Breakthrough Device designation (''Breakthrough Device Indication''):

ICD-10-CM Code Range	Description of Code Range
M86.10 - M86.19	Other acute osteomyelitis
M86.20 - M86.29	Subacute osteomyelitis
M86.30 - M86.39	Chronic multifocal osteomyelitis
M86.40 - M86.49	Chronic osteomyelitis with draining sinus
M86.50 - M86.59	Other chronic hematogenous osteomyelitis
M86.60 - M86.69	Other chronic osteomyelitis
M86.8X0 - M86.8X9	Other osteomyelitis
M86.9	Osteomyelitis, unspecified

With respect to the cost criterion, the applicant identified candidate cases using ICD–10–PCS procedure and ICD–10–CM diagnosis codes, which are detailed in the tables in this section. With these codes identified, the applicant then went through the Grouper logic in the MS–DRG v39.0 Definitions Manual and located where cases with these codes would be assigned in the MS–DRG system. This process yielded 13 MS–DRGs which the applicant used for their analysis. The applicant also submitted an additional subanalysis using only cases from the applicant's top three identified MS–DRGs (464, 493, and 504), to demonstrate that the technology meets the cost criterion.

Under the first analysis, the applicant searched claims in the FY 2019

MedPAR final rule dataset within the 13 identified MS–DRGs that reported one of the M86 ICD–10–CM diagnosis codes listed previously in combination with the ICD–10–PCS procedure codes listed in the following table, which identify procedures that could involve the use of CERAMENT® G as an adjunct to systemic antibiotic therapy and surgical debridement where there is a need for supplemental bone void filler material.

BILLING CODE 4120–01–P

ICD-10-PCS Code	Description
0PBK0ZZ	Excision of right ulna, open approach
0PBL0ZZ	Excision of left ulna, open approach
0PDK0ZZ	Extraction of right ulna, open approach
0PDL0ZZ	Extraction of left ulna, open approach
0PBC0ZZ	Excision of right humeral head, open approach
0PBD0ZZ	Excision of left humeral head, open approach
0PBF0ZZ	Excision of right humeral shaft, open approach
0PBG0ZZ	Excision of left humeral shaft, open approach
0PDF0ZZ	Extraction of right humeral shaft, open approach
0PDG0ZZ	Extraction of left humeral shaft, open approach
0PTC0ZZ	Resection of right humeral head, open approach
0PTD0ZZ	Resection of left humeral head, open approach
0PTF0ZZ	Resection of right humeral shaft, open approach
0PTG0ZZ	Extraction of left humeral shaft, open approach
0PCC0ZZ	Extirpation of matter from right humeral head, open approach
0PCF0ZZ	Extirpation of matter from right humeral shaft, open approach
0PCG0ZZ	Extirpation of matter from left humeral shaft, open approach
0PDC0ZZ	Extraction of right humeral head, open approach
0PDD0ZZ	Extraction of left humeral head, open approach
0PDF0ZZ	Extraction of right humeral shaft, open approach
0PDG0ZZ	Extraction of left humeral shaft, open approach
0QBG0ZZ	Excision of right tibia, open approach
0QBH0ZZ	Excision of left tibia, open approach
0QBJ0ZZ	Excision of right fibula, open approach
0QBK0ZZ	Excision of left fibula, open approach
0QCG0ZZ	Extirpation of matter from right tibia, open approach
0QCH0ZZ	Extirpation of matter from left tibia, open approach
0QCJ0ZZ	Extirpation of matter from right fibula, open approach
0QCK0ZZ	Extirpation of matter from left fibula, open approach
0QDG0ZZ	Extraction of right tibia, open approach
0QDH0ZZ	Extraction of left tibia, open approach
0QDJ0ZZ	Extraction of right fibula, open approach
0QDK0ZZ	Extraction of left fibula, open approach
OPCD0ZZ	Extirpation of matter from left humeral head, open approach
0MR507Z	Replace of r wrist bursa/lig with autol sub, open approach
0MR50JZ	Replace of r wrist bursa/lig with synth sub, open approach
0MR50KZ	Replace of r wrist bursa/lig with nonautol sub, open approach
0P9H00Z	Drainage of right radius, open approach
0P9J00Z	Drainage of left radius, open approach
0P9K00Z	Drainage of right ulna, open approach
0P9L00Z	Drainage of left ulna, open approach
0PCH0ZZ	Extirpation of matter from right radius, open approach
0PCJ0ZZ	Extirpation of matter from left radius, open approach

ICD-10-PCS Code	Description
0PCK0ZZ	Extirpation of matter from right ulna, open approach
0PCL0ZZ	Extirpation of matter from left ulna, open approach
0PCMOZZ	Extirpation of matter from right carpal, open approach
0PCN0ZZ	Extirpation of matter from left carpal, open approach
0Q9200Z	Drainage of right pelvic bone, open approach
0Q9300Z	Drainage of right pelvic bone with drain dev, perc approach
0Q9400Z	Drainage of r pelvic bone with drain dev, perc endo approach
0Q9500Z	Drainage of left acetabulum, open approach
0QC20ZZ	Extirpation of matter from right pelvic bone, open approach
0QC30ZZ	Extirpation of matter from left pelvic bone, open approach
0QC40ZZ	Extirpation of matter from right acetabulum, open approach
0QC50ZZ	Extirpation of matter from left acetabulum, open approach
0PC9C0ZZ	Drainage of right humeral head, open approach
0P9D00Z	Drainage of left humeral head, open approach
0P9F00Z	Drainage of right humeral shaft, open approach
0P9G00Z	Drainage of left humeral shaft, open approach
0Q9G00Z	Drainage of right tibia, open approach
0Q9H00Z	Drainage of left tibia, open approach
0Q9J00Z	Drainage of right fibula, open approach
0Q9K00Z	Drainage of left fibula, open approach
0QCG0ZZ	Extirpation of matter from right tibia, open approach
0QCJ0ZZ	Extirpation of matter from right fibula, open approach
0S9F00Z	Drainage of right ankle joint, open approach
0S9G00Z	Drainage of left ankle joint, open approach
0P9700Z	Drainage of r glenoid cav with drain dev, open approach
0P9800Z	Drainage of l glenoid cav with drain dev, open approach
0P9C00Z	Drainage of right humeral head with drain dev, open approach
0P9D00Z	Drainage of left humeral head with drain dev, open approach
0P5H0ZZ	Destruction of right radius, open approach
0P5J0ZZ	Destruction of left radius, open approach
0PBH0ZZ	Excision of right radius, open approach
0PBJ0ZZ	Excision of left radius, open approach
0Q9600Z	Drainage of right upper femur, open approach
0Q9700Z	Drainage of left upper femur, open approach
0Q9800Z	Drainage of right femoral shaft, open approach
0Q9900Z	Drainage of left femoral shaft, open approach
0Q9B00Z	Drainage of right lower femur, open approach
0Q9C00Z	Drainage of left lower femur, open approach
0Q9D00Z	Drainage of right patella, open approach
0Q9F00Z	Drainage of left patella, open approach
0QB80ZZ	Excision of right femoral shaft, open approach
0QB90ZZ	Excision of left femoral shaft, open approach
0QBB0ZZ	Excision of right lower femur, open approach
0QBC0ZZ	Excision of left lower femur, open approach
0QBG0ZZ	Excision of right tibia, open approach

ICD-10-PCS Code	Description
0QBH0ZZ	Excision of left tibia, open approach
0QBJ0ZZ	Excision of right fibula, open approach
0QBK0ZZ	Excision of left fibula, open approach
0QB60ZZ	Excision of right upper femur, open approach
0QD80ZZ	Extraction of right femoral shaft, open approach
0QD90ZZ	Extraction of left femoral shaft, open approach
0QDBOZZ	Extraction of right lower femur, open approach
0QDC0ZZ	Extraction of left lower femur, open approach
0QDG0ZZ	Extraction of right tibia, open approach
0QDH0ZZ	Extraction of left tibia, open approach
0QDJ0ZZ	Extraction of right fibula, open approach
0QDK0ZZ	Extraction of left fibula, open approach
0Q560ZZ	Destruction of right upper femur, open approach
0Q570ZZ	Destruction of left upper femur, open approach
0QB60ZZ	Excision of right upper femur, open approach
0QB70ZZ	Excision of left upper femur, open approach
0QC70ZZ	Extirpation of matter from left upper femur, open approach
0QD20ZZ	Extraction of right pelvic bone, open approach
0QD30ZZ	Extraction of left pelvic bone, open approach
0QD60ZZ	Extraction of right upper femur, open approach
0QD70ZZ	Extraction of left upper femur, open approach
0QC60ZZ	Extirpation of matter from right upper femur, open approach
0QT60ZZ	Resection of right upper femur, open approach
0QT70ZZ	Resection of left upper femur, open approach
0QBM0ZZ	Excision of left tarsal, open approach
0QDL0ZZ	Extraction of right tarsal, open approach
0QDM0ZZ	Extraction of left tarsal, open approach
0Q9N00Z	Drainage of right metatarsal, open approach
0Q9P00Z	Drainage of left metatarsal, open approach
0QBP0ZZ	Excision of left metatarsal, open approach
0QDN0ZZ	Extraction of right metatarsal, open approach
0QDP0ZZ	Extraction of left metatarsal, open approach
0P5K0ZZ	Destruction of right ulna, open approach
0P5L0ZZ	Destruction of left ulna, open approach
0PBK0ZZ	Excision of right ulna, open approach
0PBL0ZZ	Excision of left ulna, open approach
0PDK0ZZ	Extraction of right ulna, open approach
0PDL0ZZ	Extraction of left ulna, open approach
0PBH0ZZ	Excision of right radius, open approach
0PBJ0ZZ	Excision of left radius, open approach
0PDH0ZZ	Extraction of right radius, open approach
0PDJ0ZZ	Extraction of left radius, open approach
0PCH0ZZ	Extirpation of matter from right radius, open approach
0PCJ0ZZ	Extirpation of matter from left radius, open approach
0PCK0ZZ	Extirpation of matter from right ulna, open approach

ICD-10-PCS Code	Description
0PCL0ZZ	Extirpation of matter from left ulna, open approach
0PC90ZZ	Extirpation of matter from right clavicle, open approach
0PCB0ZZ	Extirpation of matter from left clavicle, open approach
0PD90ZZ	Extraction of right clavicle, open approach
0PDB0ZZ	Extraction of left clavicle, open approach
0PB90ZZ	Excision of right clavicle, open approach
0PBB0ZZ	Excision of left clavicle, open approach
0PC50ZZ	Extirpation of matter from right scapula, open approach
0PC60ZZ	Extirpation of matter from left scapula, open approach
0PD50ZZ	Extraction of right scapula, open approach
0PD60ZZ	Extraction of left scapula, open approach
0PB50ZZ	Excision of right scapula, open approach
0PB60ZZ	Excision of left scapula, open approach
0PB73ZZ	Excision of right glenoid cavity, percutaneous approach
0PB74ZZ	Excision of right glenoid cavity, perc endo approach
0PB83ZZ	Excision of left glenoid cavity, percutaneous approach
0PB84ZZ	Excision of left glenoid cavity, perc endo approach
0QBQ0ZZ	Excision of right toe phalanx, open approach
0QBR0ZZ	Excision of left toe phalanx, open approach
0QDQ0ZZ	Extraction of right toe phalanx, open approach
0QDR0ZZ	Extraction of left toe phalanx, open approach

The applicant identified 11,620 cases across 13 MS–DRGs as identified in the table that follows:

MS-DRG	Description
463	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with MCC
464	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with CC
492	Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC
493	Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with CC
495	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur with MCC
496	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur with CC
498	Local Excision and Removal Internal Fixation Devices of Hip and Femur with CC/MCC
503	Foot Procedures with MCC
504	Foot Procedures with CC
510	Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with MCC
511	Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with CC
515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC
516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC

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The applicant noted that candidate cases for CERAMENT® G with osteomyelitis would qualify for the CC/MCC MS–DRGs because osteomyelitis is listed in the Grouper as a CC condition. Therefore, the applicant concluded that cases with osteomyelitis would not be grouped in the uncomplicated MS–DRGs (for example, 465, 494, etc.). The applicant stated that because osteomyelitis is never assigned to uncomplicated surgical MS–DRGs, it excluded uncomplicated MS–DRGs from its analysis.

The applicant then removed charges for the prior technology that may be replaced by CERAMENT® G. The applicant conducted a market analysis that identified 3 types of prior technology devices: Poly(methyl methacrylate) (PMMA) manually mixed with antibiotics, PMMA pre-loaded with antibiotics, and calcium sulfate (CaS) mixed with antibiotics. The applicant researched the average sales price (ASP) for major competitors for 5cc and 10cc of each device type and calculated a weighted average cost of $444 per 5cc and $727 per 10cc.[202] Then the applicant converted costs to charges by dividing costs by the Supplies &

[202] The applicant's analysis was informed by 2019 and 2020 data for Osteoset, Stimulan, and Calcigen S (calcium sulfates mixed with antibiotics), Palacos, Cobalt (PMMA manually mixed with antibiotics), Cobalt G, Biomet Bone Cement R, and Refobacin Bone Cement R (PMMA pre-loaded with antibiotics) from three sources: an iData Market Research 2019 Sku Data Report, Global Data US Hospital Bone Grafts and Substitutes Q3 2019 Report, and feedback from sales representatives in the field.

Equipment CCR of 0.297 (86 FR 44966). Using this CCR, $444 per 5cc and $727 per 10cc yielded an estimated hospital charge of prior technologies of $1,495 per 5cc and $2,449 per 10cc. The applicant explained that the total amount of antibiotics depends on the amount of product required for different sized bones. The applicant then standardized the charges and applied a 4-year inflation factor of 1.281834 based on the inflation factor used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542).

The applicant added estimated charges for the new technology by dividing the estimated, expected hospital list price for the device (based on expected 5/10/15 cc costs for CERAMENT® G, by MS–DRG), by the aforementioned Supplies & Equipment CCR of 0.297.

The applicant calculated a final inflated case-weighted average standardized charge per case of $135,258 and an average case-weighted threshold of $86,603. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

The applicant also provided an alternate cost analysis using the applicant's top three identified MS–DRGs (464, 493, and 504), which together constituted more than half of the applicant's identified cases. Using the same methodology and data sources noted previously, the applicant calculated a final inflated case-weighted average standardized charge per case of $112,316 and an average case-weighted threshold of $77,375. The applicant maintained that CERAMENT® G meets the cost criterion under this alternate analysis.

We stated in the proposed rule that we agree with the applicant that CERAMENT® G meets the cost criterion and therefore, subject to the technology receiving FDA marketing authorization for use as a bone-void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis by July 1, 2022, we proposed to approve CERAMENT® G for new technology add-on payments for FY 2023.

Based on preliminary information from the applicant at the time of the proposed rule, the total cost of CERAMENT® G for a typical patient was determined to be $7,567 per procedure. Per the applicant, the amount of CERAMENT® G used per patient depends on the complexity of the patient's injury, subsequent comorbidities, as well as the location and size of the bone void. The applicant expects that an average patient will require ~10cc per procedure, based on the case weighted volume of expected utilization across the MS–DRGs. From this weighted average, the applicant derived the average, weighted cost of $7,567 per patient. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the product CERAMENT® G would be $4,918.55 for FY 2022 (that is, 65% of the average cost of the technology).

We invited public comments on whether CERAMENT® G meets the cost criterion and our proposal to approve new technology add-on payments for CERAMENT® G for FY 2023, subject to CERAMENT® G receiving FDA marketing authorization for use as a bone-void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis by July 1, 2022.

Comment: We received a public comment urging CMS to finalize its proposals to approve new technology add-on payments for multiple technologies for FY 2023, including CERAMENT G®, in order to foster innovation and make life and ability-saving devices more readily available to patients.

Response: We appreciate the comment.

Based on the information provided in the application for new technology add-on payments, we believe CERAMENT® G meets the cost criterion. The technology received FDA De Novo marketing authorization on May 17, 2022 with an indication for use as a bone void filler in skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis in defects in the extremities, that is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for CERAMENT® G for FY 2023. We consider the beginning of the newness period to commence on May 17, 2022, the date on which the technology received its FDA De Novo marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of CERAMENT® G is $7,567.00. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of CERAMENT® G is $4,918.55 for FY 2023 (that is, 65% of the average cost of the technology). Cases involving the use of CERAMENT® G that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7).

(2) GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device)

W.L. Gore and Associates, Inc., submitted an application for new technology add-on payments for the GORE® TAG® Thoracic Branch Endoprosthesis (TBE) device for FY 2023. According to the applicant, the GORE® TAG® TBE device is a modular device consisting of three components, an Aortic Component, a Side Branch Component, and an optional Aortic Extender Component, each of which is pre-mounted on a catheter delivery system for treatment of thoracic aortic aneurysms, traumatic aortic transection, and aortic dissection.

According to the applicant, the GORE® TAG® TBE device was granted designation under the Expedited Access Pathway (EAP) by FDA (and is therefore considered part of the Breakthrough Devices Program by FDA) on July 17, 2015, for endovascular repair of descending thoracic aortic and aortic arch for patients who have appropriate anatomy. The applicant indicated that it anticipated receiving premarket approval of the GORE® TAG® TBE device as a Class III device from FDA in Spring 2022 with a proposed indication for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who have adequate iliac/femoral access, and eligible proximal aorta, left subclavian, or distal landing zones (isolated lesion patients only). We noted in the proposed rule that since the indication for which the applicant anticipated receiving premarket approval was included within the scope of the EAP designation, it appeared that the

proposed PMA indication was appropriate for new technology add-on payment under the alternative pathway criteria. Subsequently, the applicant received premarket approval on May 13, 2022 with an indication for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who are at high risk for debranching subclavian procedures and who have appropriate anatomy, which is within the scope of the EAP designation.

The applicant noted that a combination of two existing ICD–10–PCS procedure codes can be used to uniquely identify the GORE® TAG® TBE: 02VW4EZ (Restriction of thoracic aorta, descending with branched or fenestrated intraluminal device, one or two arteries, percutaneous endoscopic approach), in combination with 02VX4EZ (Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous endoscopic approach). Per the applicant, the GORE® TAG® TBE device is placed such that it straddles two anatomic regions, the descending thoracic aorta and thoracic aortic arch, thereby necessitating the use of both ICD–10–PCS procedure codes to accurately describe the use of the device.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR dataset from the FY 2022 IPPS proposed rule for cases reporting a combination of a thoracic endovascular repair (TEVAR) procedure and a bypass procedure. The applicant listed the following ICD–10–PCS codes for TEVAR procedures and bypass procedures, which the applicant used to identify potential cases that may be eligible for treatment with the GORE® TAG® TBE device. Per the applicant, cases with at least one ICD–10–PCS procedure code from each category were included in the analysis.

ICD-10-PCS	Description
Codes Identifying TEVAR Procedure	
02VW3DZ	Restriction of thoracic aorta, descending with intraluminal device, percutaneous approach
02VW4DZ	Restriction of thoracic aorta, descending with intraluminal device, percutaneous endoscopic approach
Codes Identifying Bypass Procedure	
03140JK	Bypass left subclavian artery to left extracranial artery with synthetic substitute, open approach
03140KK	Bypass left subclavian artery to left extracranial artery with an autologous tissue substitute, open approach
03140ZK	Bypass left subclavian artery to left extracranial artery, open approach
03150J1	Bypass right axillary artery to left upper arm artery with synthetic substitute, open approach
03160JK	Bypass left axillary artery to left extracranial artery with synthetic substitute, open approach
031J0JK	Bypass left common carotid artery to left extracranial artery with synthetic substitute, open approach
031J0JY	Bypass left common carotid artery to upper artery with synthetic substitute, open approach
03S40ZZ	Reposition left subclavian artery, open approach
03S43ZZ	Reposition left subclavian artery, percutaneous approach
03SQ0ZZ	Reposition left vertebral artery, open approach
03SQ3ZZ	Reposition left vertebral artery, percutaneous approach

MS-DRG	Description	%Cases
220	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC	41.0%
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	36.7%
221	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC	11.9%
003	ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures	5.2%
216	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC	5.2%

The applicant identified 210 cases mapping to five MS–DRGs. The applicant then removed charges for the technology being replaced. The applicant stated that the use of TAG® Conformable devices in cases that also use the GORE® TAG® TBE device is entirely dependent on the patient's anatomy. The applicant explained that the average case utilizing the GORE® TAG® TBE device uses 0.6 TAG® Conformable devices, compared to an average of 1.4 TAG® Conformable devices per procedure for current TEVAR cases, resulting in a difference of 0.8 TAG® Conformable devices which will no longer be used in cases utilizing the GORE® TAG® TBE device. Accordingly, 80% of all device implant charges were removed from the claims to be conservative, per the applicant. The applicant then removed other charges related to the prior technology. According to the applicant, a research study [203] that compared 24 patients treated with TBE to 31 patients treated with the traditional method at one facility found that TBE device cases have a 19% reduction in operating room (OR) time compared to the OR time for the combined procedures (TEVAR with a bypass procedure), and a 48% reduction in length of stay. Accordingly, the applicant removed 19% of OR charges (revenue code 0360), removed 48% of routine charges (revenue code 01XX) when a claim showed routine charges, and removed 48% of intensive care unit (ICU) charges if a claim included no routine charges. The applicant then standardized the charges and applied a 4-year inflation factor of 1.2818 based on the inflation factor used in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45538), to update the charges from FY 2019 to FY 2023. The applicant then added charges for the new technology by dividing the average per patient cost of the GORE® TAG® TBE device by the national CCR for implantable devices (0.293) from the FY

[203] Shultze W, Baxter R, Gable C, et al. Comparison Of Surgical Debranching Versus Branched Endografts In Zone 2 TEVAR. Oral presentation at the Society for Vascular Surgery Meeting; March 2021, Miami FL. *https://symposium.scvs.org/abstracts/2021/M76.cgi.*

2022 IPPS/LTCH PPS final rule (86 FR 44966). The applicant calculated a final inflated case-weighted average standardized charge per case of $400,515 and an average case-weighted threshold of $217,182. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28324), we noted that the charges removed for prior technology are based on length of stay in a small study conducted at a single institution. Specifically, the study involved 24 patients who received the TBE device during elective procedures and 31 who had the procedures with bypass. Three of these procedures were emergent and only 14 and 17, respectively, were procedures in Zone 2 where the GORE® TAG® TBE would be indicated. Given the small percentage of procedures that directly relate to the proposed GORE® TAG® TBE indication, we questioned the extent to which these results are generalizable to the cost analysis performed above and the greater Medicare population. Additionally, the applicant did not specify the revenue codes used to identify and remove intensive care unit charges. We noted the applicant listed two ICD–10–PCS codes (03S43ZZ and 03SQ3ZZ) in their analysis which are percutaneous procedures and questioned whether the inclusion of these codes was appropriate as the devices currently used to repair the aortic arch require the creation of a bypass performed in an open surgery. We also questioned whether the cases that the applicant identified were appropriately representative of cases eligible for treatment with GORE® TAG® TBE and requested additional information to clarify this issue.

Subject to the applicant adequately addressing these concerns, we stated in the proposed rule that we agreed that the technology meets the cost criterion and therefore proposed to approve the GORE® TAG® TBE device for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization for the proposed indication by July 1, 2022.

Based on preliminary information from the applicant at the time of the proposed rule, the per-patient anticipated hospital cost of the GORE® TAG® TBE device was $42,780. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. In the proposed rule, we stated that in the event we were to receive supplemental information from the applicant to adequately address our concerns regarding the cost criterion, and we were to approve new technology add-on payments for the GORE® TAG® TBE device in the final rule, the maximum new technology add-on payment for a case involving the use of the GORE® TAG® TBE device would be $27,807 for FY 2023 (that is, 65% of the average cost of the technology).

We invited public comments on whether the GORE® TAG® TBE device meets the cost criterion and our proposal to approve new technology add-on payments for the GORE® TAG® TBE device for FY 2023, subject to the technology receiving FDA marketing authorization for the proposed indication that corresponds to the EAP designation by July 1, 2022.

Comment: The applicant provided comments and a revised cost analysis in response to CMS' concerns identified in the proposed rule. With respect to the concern that the charges removed for prior technology were based on length of stay in a small study conducted at a single institution, the applicant stated that the pivotal trial for the GORE® TAG® TBE device was conducted at 40 U.S. sites and the separate outcome sub-study was based at a site that had the highest numbers of enrolled participants. In addition, the applicant stated that the length of stay and length of time in the ICU was similar for all sites in the clinical trial and therefore the cost estimates from a single institution are reflective of the cost of care provided at other sites.

With respect to the concern about results being generalizable to the greater Medicare population, the applicant stated that the median age of outcome sub-study participants was 65 years, and that half of all participants were of Medicare-eligible age. The applicant also noted that the outcome sub-study population (24 GORE® TAG® TBE patients and 31 SR–TEVAR patients) represented more than a quarter of a total of 202 GORE® TAG® TBE-eligible cases in the FY 2019 Medicare claims. Per the applicant, this sample of the 202 eligible cases in the FY 2019 Medicare claims is large enough to appropriately estimate the costs associated with the GORE® TAG® TBE procedure and that, based on the median age, the estimate is generalizable to the Medicare population.

With respect to the concern as to whether the cases identified by the applicant were appropriately representative of cases eligible for treatment with GORE® TAG® TBE, the applicant stated that the GORE® TAG® TBE device replaces two separate operating room procedures: a left subclavian artery (SA) bypass procedure, usually an open surgery, and a percutaneous thoracic endograft implant procedure, commonly referred to as SR–TEVAR, because it contains a branched element that is inserted into the left subclavian artery thereby maintaining blood flow and eliminating the need for a SA bypass procedure. The applicant stated that the outcome sub-study provides information on resource use differences between patients undergoing TBE procedures compared to a combination of surgical revascularization and thoracic endograft implant. The applicant stated that including cases that involved both procedures (that is, the SA bypass procedure and the TEVAR procedure) in the cost criterion analysis and removing 100% of device charges as well as other related service charges (19% of OR charges and 48% of routine care charges) better reflects the estimate of the GORE® TAG® TBE standardized charges. In the updated analysis, the applicant removed 100% of all device charges from the MedPAR cases compared to removing 80%, which it did in its original application.

The applicant further indicated that while every patient presentation of aortic disease is unique in length, type, and severity of disease, all patients in the outcome sub-study had serious aortic disease that needed repair in the left subclavian artery, even if cases were characterized as an elective surgery for purposes of the study reporting. The applicant also stated that the ends of the device must exceed the length of the diseased aorta on both ends, the proximal and distal locations of the implanted device varied, depending on the length of the aortic disease, and as such, the devices can span several zones. The applicant further noted that all cases, emergent or elective, had similar resource use.

With respect to the concern that the revenue codes used to identify and remove intensive care unit charges were not specified, the applicant stated that it used CMS revenue codes 020x and 021x to identify intensive care unit charges in the rate-setting methodology. We note that revenue code descriptions for 021x and 021x are Intensive Care Unit and Coronary Care Unit, respectively.

With respect to our inquiry about the inclusion of two codes for percutaneous procedures, the applicant explained that it included the two percutaneous approach codes in its original cost analysis in order to pick up all bypass surgery codes. The applicant then explained that eliminating these two codes from the inclusion criteria for the revised analysis excluded only one case. The applicant noted that removing the one percutaneous SA bypass case limited the revised cost criterion analysis to only those cases where the subclavian artery bypass surgery was coded as an open approach.

The applicant reported that the updated cost criterion analysis resulted in a threshold amount of $217,080 and a new standardized charge estimate of $377,857. The applicant stated that the new standardized charge estimate still greatly exceeds the new technology add-on payment threshold and the GORE® TAG® TBE device meets the cost criterion requirement.

The applicant also stated that upon further consultation with clinical experts, the better combination of ICD–10–PCS codes to identify cases utilizing the technology would be 02VW3DZ (Restriction of thoracic aorta, descending with intraluminal device, percutaneous approach), in combination with 02VX3EZ (restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach) and requested that these codes be used to identify the GORE® TAG® TBE for purposes of new technology add-on payment instead of the codes included in the proposed rule.

Another commenter familiar with the applicant's cost study submitted a public comment reiterating the applicant's statements regarding the characteristics of the single institution upon which the applicant's cost analysis was based, disease severity in the patient population, the uniform requirement of Zone 2 repair despite variation of distal zones treated, and generalizability of the study population to the Medicare population. Based on the results achieved for patients receiving the TBE graft as compared to the TEVAR and subclavian artery bypass, this commenter recommended that CMS approve the GORE® TAG® TBE for new technology add on payments.

Response: We thank the commenters for their comments and appreciate the additional clarification regarding the cost criterion. Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the GORE® TAG® Thoracic Branch Endoprosthesis (TBE) meets the cost criterion. GORE® TAG® TBE received marketing authorization from FDA on May 13, 2022 for the indication covered by its Breakthrough Device designation for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who are at high risk for debranching subclavian procedures and who have appropriate anatomy. Therefore, we are finalizing our proposal to approve new technology add-on payments for the GORE® TAG® TBE for FY 2023 and we consider the beginning of the newness period to commence on May 13, 2022, which is the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information at the time of this final rule, the cost per case of the GORE® TAG® TBE is $42,780. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the GORE® TAG® TBE is $27,807 for FY 2023 (that is, 65% of the average cost of the technology). Cases involving the use of GORE® TAG® TBE that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes: 02VW3DZ (Restriction of thoracic aorta, descending with intraluminal device, percutaneous approach) in combination with 02VX3EZ (Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach).

(3) iFuse Bedrock Granite Implant System

SI–BONE, Inc., submitted an application for new technology add-on payments for the iFuse Bedrock Granite Implant System for FY 2023. According to the applicant, the iFuse Bedrock Granite Implant System is a sterile, single-use permanent implant intended to provide sacropelvic fusion of the sacroiliac joint and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion. The applicant stated that the joint fusion occurs as a result of the device's porous surface and interstices, and fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection. Per the applicant, the iFuse Bedrock Granite Implant System can be placed into the pelvis in two trajectories: sacroalar-iliac (SAI) trajectory (that is, into the sacrum, across the SI joint and into the ilium) or directly into the ilium, and joint fusion occurs only when the SAI trajectory is used.

According to the applicant, the iFuse Bedrock Granite Implant System received FDA Breakthrough Device designation on November 23, 2021 for sacropelvic fixation and as an adjunct for sacroiliac joint fusion (when used with commercially available sacroiliac joint fusion promoting devices) in conjunction with commercially available posterior pedicle screw systems for the treatment of the acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine; degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion; spondylolisthesis; trauma (that is, fracture or dislocation); spinal stenosis; deformities or curvatures (that is, scoliosis, kyphosis, and/or lordosis); spinal tumor; pseudarthrosis; and/or failed previous fusion. Subsequently, the iFuse Bedrock Granite Implant System received 510(k) clearance from FDA on May 26, 2022 (K220195) for the same indication.

The applicant stated that ICD–10–PCS codes that may be utilized to describe the placement of an internal fixation device into the pelvic bone or acetabulum, listed in the following table, do not distinctly identify the iFuse Bedrock Granite Implant System.

ICD-10-PCS	Description
0QH204Z	Insertion of internal fixation device into right pelvic bone, open approach
0QH304Z	Insertion of internal fixation device into left pelvic bone, open approach
0SG734Z	Fusion of right sacroiliac joint with internal fixation device, percutaneous approach
0SG834Z	Fusion of left sacroiliac joint with internal fixation device, percutaneous approach
0SG804Z	Fusion of left sacroiliac joint with internal fixation device, open approach
0SG704Z	Fusion of right sacroiliac joint with internal fixation device, open approach

The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2023 and was granted approval to identify the iFuse Bedrock Granite Implant System using the following procedure codes effective October 1, 2022:

ICD-10-PCS	Description
XNH6058	Insertion of internal fixation device with tulip connector into right pelvic bone, open approach, new technology group 8
XNH6358	Insertion of internal fixation device with tulip connector into right pelvic bone, percutaneous approach, new technology group 8
XNH7058	Insertion of internal fixation device with tulip connector into left pelvic bone, open approach, new technology group 8
XNH7358	Insertion of internal fixation device with tulip connector into left pelvic bone, percutaneous approach, new technology group 8
XRGE058	Fusion of right sacroiliac joint using internal fixation device with tulip connector, open approach, new technology group 8
XRGE358	Fusion of right sacroiliac joint using internal fixation device with tulip connector, percutaneous approach, new technology group 8
XRGF058	Fusion of left sacroiliac joint using internal fixation device with tulip connector, open approach, new technology group 8
XRGF358	Fusion of left sacroiliac joint using internal fixation device with tulip connector, percutaneous approach, new technology group 8

With regard to the cost criterion, the applicant conducted two analyses based on 100% of identified claims and 78% of identified claims. To identify potential cases where the iFuse Bedrock Granite Implant System could be utilized, the applicant searched the FY 2019 MedPAR final rule file for claims reporting a combination of at least one of the ICD–10–PCS procedure codes for the placement of an internal fixation device into the pelvic bone or acetabulum, noted previously, and at least one of the following ICD–10–CM diagnosis codes used to describe the indication under the Breakthrough Device designation.

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ICD-10-CM	Description
M40.00	Postural kyphosis, site unspecified
M40.04	Postural kyphosis, thoracic region
M40.05	Postural kyphosis, thoracolumbar region
M40.10	Other secondary kyphosis, site unspecified
M40.13	Other secondary kyphosis, cervicothoracic region
M40.14	Other secondary kyphosis, thoracic region
M40.15	Other secondary kyphosis, thoracolumbar region
M40.204	Unspecified kyphosis, thoracic region
M40.205	Unspecified kyphosis, thoracolumbar region
M40.209	Unspecified kyphosis, site unspecified
M40.294	Other kyphosis, thoracic region
M40.295	Other kyphosis, thoracolumbar region
M40.35	Flatback syndrome, thoracolumbar region
M40.36	Flatback syndrome, lumbar region
M40.37	Flatback syndrome, lumbosacral region
M40.40	Postural lordosis, site unspecified
M40.45	Postural lordosis, thoracolumbar region
M40.46	Postural lordosis, lumbar region
M40.47	Postural lordosis, lumbosacral region
M40.55	Lordosis, unspecified, thoracolumbar region
M40.56	Lordosis, unspecified, lumbar region
M40.57	Lordosis, unspecified, lumbosacral region
M41.124	Adolescent idiopathic scoliosis, thoracic region
M41.125	Adolescent idiopathic scoliosis, thoracolumbar region
M41.126	Adolescent idiopathic scoliosis, lumbar region
M41.127	Adolescent idiopathic scoliosis, lumbosacral region
M41.129	Adolescent idiopathic scoliosis, site unspecified
M41.20	Other idiopathic scoliosis, site unspecified
M41.24	Other idiopathic scoliosis, thoracic region
M41.25	Other idiopathic scoliosis, thoracolumbar region
M41.26	Other idiopathic scoliosis, lumbar region
M41.27	Other idiopathic scoliosis, lumbosacral region
M41.30	Thoracogenic scoliosis, site unspecified
M41.34	Thoracogenic scoliosis, thoracic region
M41.35	Thoracogenic scoliosis, thoracolumbar region
M41.40	Neuromuscular scoliosis, site unspecified
M41.45	Neuromuscular scoliosis, thoracolumbar region
M41.46	Neuromuscular scoliosis, lumbar region
M41.47	Neuromuscular scoliosis, lumbosacral region
M41.50	Other secondary scoliosis, site unspecified
M41.54	Other secondary scoliosis, thoracic region
M41.55	Other secondary scoliosis, thoracolumbar region
M41.56	Other secondary scoliosis, lumbar region
M41.57	Other secondary scoliosis, lumbosacral region
M41.84	Other forms of scoliosis, thoracic region
M41.85	Other forms of scoliosis, thoracolumbar region
M41.86	Other forms of scoliosis, lumbar region
M41.87	Other forms of scoliosis, lumbosacral region
M42.10	Adult osteochondrosis of spine, site unspecified
M42.14	Adult osteochondrosis of spine, thoracic region

ICD-10-CM	Description
M42.15	Adult osteochondrosis of spine, thoracolumbar region
M42.16	Adult osteochondrosis of spine, lumbar region
M42.17	Adult osteochondrosis of spine, lumbosacral region
M42.18	Adult osteochondrosis of spine, sacral and sacrococcygeal region
M42.19	Adult osteochondrosis of spine, multiple sites in spine
M43.15	Spondylolisthesis, thoracolumbar region
M43.16	Spondylolisthesis, lumbar region
M43.17	Spondylolisthesis, lumbosacral region
M43.18	Spondylolisthesis, sacral and sacrococcygeal region
M43.19	Spondylolisthesis, multiple sites in spine
M43.8X5	Other specified deforming dorsopathies, thoracolumbar region
M43.8X6	Other specified deforming dorsopathies, lumbar region
M43.8X7	Other specified deforming dorsopathies, lumbosacral region
M43.8X8	Other specified deforming dorsopathies, sacral and sacrococcygeal region
M43.8X9	Other specified deforming dorsopathies, site unspecified
M43.9	Deforming dorsopathy, unspecified
M48.26	Kissing spine, lumbar region
M48.27	Kissing spine, lumbosacral region
M48.36	Traumatic spondylopathy, lumbar region
M48.37	Traumatic spondylopathy, lumbosacral region
M53.2X6	Spinal instabilities, lumbar region
M53.2X7	Spinal instabilities, lumbosacral region
M53.2X8	Spinal instabilities, sacral and sacrococcygeal region
M53.3	Sacrococcygeal disorders, not elsewhere classified

For the analysis using 100% of cases, the applicant identified 2,165 cases mapping to the following 26 MS–DRGs:

MS-DRG	Description
028	Spinal Procedures with MCC
029	Spinal Procedures with CC or Spinal Neurostimulators
252	Other Vascular Procedures with MCC
453	Combined Anterior and Posterior Spinal Fusion with MCC
454	Combined Anterior and Posterior Spinal Fusion with CC
455	Combined Anterior and Posterior Spinal Fusion without CC/MCC
456	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC
457	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with CC
458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions without CC/MCC
459	Spinal Fusion Except Cervical with MCC
460	Spinal Fusion Except Cervical without MCC
496	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur with CC
515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC
516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC
517	Other Musculoskeletal System and Connective Tissue O.R. Procedures without CC/MCC
518	Back and Neck Procedures Except Spinal Fusion with MCC or Disc Device or Neurostimulator
519	Back and Neck Procedures Except Spinal Fusion with CC
628	Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC
854	Infectious and Parasitic Diseases with O.R. Procedures with CC
856	Postoperative or Post-Traumatic Infections with O.R. Procedures with MCC
907	Other O.R. Procedures for Injuries with MCC
908	Other O.R. Procedures for Injuries with CC
957	Other O.R. Procedures for Multiple Significant Trauma with MCC
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
982	Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC

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The applicant then removed 50% of the charges associated with medical supplies and implantable devices (revenue centers 027x and 0624). The applicant stated that the removal of 50% of the charges associated with medical supplies and implantable devices reflects a conservative estimate as the iFuse Bedrock Granite Implant System is used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion. The applicant then standardized the charges and applied the three-year inflation factor of 20.4% used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542) to update the charges from FY 2019 to FY 2022. The applicant then added charges for the new technology by dividing the per-patient anticipated hospital cost of the iFuse Bedrock Granite Implant System by the national average cost-to-charge ratio for implantable devices (0.239) from the FY 2022 IPPS/LTCH PPS final rule. Under the analysis based on 100% of identified claims, the applicant calculated a final inflated case-weighted average standardized charge per case of $254,264 and an average case-weighted threshold of $159,841.

For the analysis using 78% of cases, the applicant identified 1,682 cases mapping to 4 MS–DRGs. The applicant conducted the same analysis noted previously and determined a final inflated case-weighted average standardized charge per case of $253,333 and an average case-weighted threshold of $164,561. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount under both analyses, the applicant asserted that the technology meets the cost criterion.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28327), we agreed with the applicant that iFuse Bedrock Granite Implant System meets the cost criterion and therefore we proposed to approve the iFuse Bedrock Granite Implant System for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2022.

Based on preliminary information from the applicant at the time of the proposed rule, the per-patient anticipated hospital cost of the iFuse Bedrock Granite Implant System was $15,120. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the iFuse Bedrock Granite Implant System would be $9,828 for FY 2023 (that is, 65% of the average cost of the technology).

We invited public comments on whether the iFuse Bedrock Granite Implant System meets the cost criterion and our proposal to approve new technology add-on payments for the iFuse Bedrock Granite Implant System for FY 2023, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2022.

Comment: We received a few comments supporting CMS' proposal to approve the iFuse Bedrock Granite Implant System for new technology add-on payments. One of the commenters also agreed with CMS that the technology meets the cost criterion.

Response: We appreciate the input from the commenters.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the iFuse Bedrock Granite Implant System meets the cost criterion. The iFuse Bedrock Granite Implant System received marketing authorization from FDA on May 26, 2022 for the indication covered by the Breakthrough Device designation, for sacropelvic fixation and as an adjunct for sacroiliac joint fusion (when used with commercially available sacroiliac joint fusion promoting devices) in conjunction with commercially available posterior pedicle screw systems for the treatment of the acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine; degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion; spondylolisthesis; trauma (that is, fracture or dislocation); spinal stenosis; deformities or curvatures (that is, scoliosis, kyphosis, and/or lordosis); spinal tumor; pseudarthrosis; and/or failed previous fusion. Therefore, we are finalizing our proposal to approve new technology add-on payments for the iFuse Bedrock Granite Implant System for FY 2023, and we consider the beginning of the newness period to commence on May 26, 2022, which is the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information at the time of this final rule, the cost per case of the iFuse Bedrock Granite Implant System is $15,120. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the iFuse Bedrock Granite Implant System is $9,828 for FY 2023 (that is, 65% of the average cost of the technology). Cases involving the use of the iFuse Bedrock Granite Implant System that are eligible for new technology add-on payments will be identified by one of the following ICD–10– PCS codes:

ICD-10-PCS	Description
XNH6058	Insertion of internal fixation device with tulip connector into right pelvic bone, open approach, new technology group 8
XNH6358	Insertion of internal fixation device with tulip connector into right pelvic bone, percutaneous approach, new technology group 8
XNH7058	Insertion of internal fixation device with tulip connector into left pelvic bone, open approach, new technology group 8
XNH7358	Insertion of internal fixation device with tulip connector into left pelvic bone, percutaneous approach, new technology group 8
XRGE058	Fusion of right sacroiliac joint using internal fixation device with tulip connector, open approach, new technology group 8
XRGE358	Fusion of right sacroiliac joint using internal fixation device with tulip connector, percutaneous approach, new technology group 8
XRGF058	Fusion of left sacroiliac joint using internal fixation device with tulip connector, open approach, new technology group 8
XRGF358	Fusion of left sacroiliac joint using internal fixation device with tulip connector, percutaneous approach, new technology group 8

(4) Thoraflex™ Hybrid Device

Terumo Aortic submitted an application for new technology-add on payments for the Thoraflex™ Hybrid Device for FY 2023. Per the applicant, the device is a sterile single-use, gelatin sealed Frozen Elephant Trunk (FET) surgical medical device. The applicant explained that the device is deployed through an opened aortic arch and then positioned into the descending thoracic aorta. The applicant further explained that, once it is completely deployed, the collar is sutured to the aorta, and graft anastomoses are then performed in a manner depending upon the chosen product design (which the applicant specified as either the Plexus or the Ante-Flo). The device includes a proximal crimped polyester surgical graft, central polyester collar, and distal nitinol ring stents supported by thin wall polyester fabric. The applicant also noted that the device has a unique gelatin sealant that acts as a seal, preventing blood loss through the polyester fabric product wall. We note that Terumo Aortic previously submitted an application for new technology add-on payments for the Thoraflex™ Hybrid Device for FY 2022, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25390) which was withdrawn prior to the issuance of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45127).

According to the applicant, the Thoraflex™ Hybrid Device received Breakthrough Device designation on March 20, 2020 for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection. The applicant received FDA marketing authorization on April 19, 2022 for the same indication as the Breakthrough Device designation. According to the applicant, the ICD–10 Coordination and Maintenance Committee approved the following ICD–10–PCS codes to specifically describe the use of the Thoraflex™ Hybrid Device, effective October 1, 2021: X2RX0N7 (Replacement of thoracic aorta arch with branched synthetic substitute with intraluminal device, new technology

group 7) and X2VW0N7 (Restriction of thoracic descending aorta with branched synthetic substitute with intraluminal device, new technology group 7).

With respect to the cost criterion, the applicant conducted two analyses based on 100% of identified claims and 74% of identified claims. To identify potential cases where the Thoraflex™ Hybrid Device could be utilized, the applicant searched the FY 2019 MedPAR file for claims reporting the following ICD–10–PCS codes for thoracic aortic replacement procedures: 02RX08Z (Replacement of thoracic aorta, ascending/arch with zooplastic tissue, open approach), 02RX0JZ (Replacement of thoracic aorta, ascending/arch with synthetic tissue, open approach), and 02RX0KZ (Replacement of thoracic aorta, ascending/arch with nonautologous tissue substitute, open approach).

For the analysis using 100% of cases, the applicant identified 5,374 cases mapping to 21 MS–DRGs. The applicant then removed charges for the technology being replaced. Per the applicant, the use of the Thoraflex™ Hybrid device is expected to replace a portion of prior technologies. The applicant explained that because an estimate of the percentage of these total charges that would be replaced could not be determined, it removed 100% of charges associated with medical/surgical supplies and devices (revenue centers 027x and 0624). The applicant then standardized the charges and applied the 3-year outlier inflation factor of 1.204686 used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542) to update the charges from FY 2019 to FY 2022. The applicant then added charges for the new technology. The applicant multiplied the cost of the technology by the national cost-to-charge ratio for implantable devices from the FY 2022 IPPS/LTCH PPS final rule (0.293) to calculate estimated average hospital charges associated with the device. Under this analysis, based on 100% of identified claims, the applicant calculated a final inflated case-weighted average standardized charge per case of $420,924 and an average case-weighted threshold of $230,659.

Under the analysis based on 74% of cases, the applicant used the same methodology, which identified 3,980 cases across MS–DRGs 219 and 220. The applicant determined the average case-weighted threshold of $211,423 and a final inflated average standardized charge per case of $373,273. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount under both analyses, the applicant asserted that the technology meets the cost criterion.

In the proposed rule, we stated that we agree with the applicant that the Thoraflex™ Hybrid Device meets the cost criterion and therefore proposed to approve the Thoraflex™ Hybrid Device for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection by July 1, 2022.

Based on preliminary information from the applicant at the time of the proposed rule, the cost of the Thoraflex™ Hybrid Device was $35,000 per patient. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of Thoraflex™ Hybrid Device would be $22,750 per patient for FY 2023 (that is, 65% of the average cost of the technology).

We invited public comments on whether the Thoraflex™ Hybrid Device meets the cost criterion and our proposal to approve new technology add-on payments for the Thoraflex™ Hybrid Device for FY 2023, subject to the Thoraflex™ Hybrid Device receiving FDA marketing authorization by July 1, 2022 for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection.

Comment: The applicant submitted a public comment expressing support for the approval of the Thoraflex™ Hybrid Device for the new technology add-on payment for FY 2023. The applicant emphasized that both X2RX0N7 (Replacement of thoracic aorta arch with branched synthetic substitute with intraluminal device, new technology group 7) and X2VW0N7 (Restriction of thoracic descending aorta with branched synthetic substitute with intraluminal device, new technology group 7) need to be reported concurrently to appropriately describe the implant procedure for the Thoraflex™ Hybrid Device.

Response: We appreciate the applicant's support.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the Thoraflex™ Hybrid Device meets the cost criterion. The Thoraflex™ Hybrid Device received marketing authorization from FDA on April 19, 2022 for the indications covered by its Breakthrough Device designation for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Thoraflex™ Hybrid Device for FY 2023, and we consider the beginning of the newness period to commence on April 19, 2022, which is the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information at the time of this final rule, the cost per case of the Thoraflex™ Hybrid Device is $35,000 per patient. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Thoraflex™ Hybrid Device is $22,750 for FY 2023 (that is, 65% of the average cost of the technology). Cases involving the use of the Thoraflex™ Hybrid Device that are eligible for new technology add-on payments will be identified by the ICD–10–PCS code X2RX0N7 (Replacement of thoracic aorta arch with branched synthetic substitute with intraluminal device, new technology group 7) in combination with the ICD–10–PCS code X2VW0N7 (Restriction of thoracic descending aorta with branched synthetic substitute with intraluminal device, new technology group 7).

(5) ViviStim® Paired VNS System

MicroTransponder, Inc. submitted an application for new technology add-on payments for the ViviStim® Paired VNS System for FY 2023. According to the applicant, the ViviStim® Paired VNS System is a paired vagus nerve stimulation therapy intended to stimulate the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve

motor function in chronic ischemic stroke patients with moderate to severe arm impairment. The applicant stated that the Vivistim® Paired VNS System is comprised of an Implantable Pulse Generator (IPG), an implantable stimulation Lead, and an external paired stimulation controller which is composed of the external Wireless Transmitter (WT) and the external Stroke Application and Programming Software (SAPS). According to the applicant, the external paired stimulation controller (SAPS and WT) enables the implanted components (the IPG and Lead) to stimulate the vagus nerve during rehabilitation. The applicant stated that patients undergo 25–30 hours of in-clinic rehabilitation over 6 weeks, where the ViviStim® Paired VNS System is actively paired with rehabilitation by a therapist. The applicant further stated that following this in-clinic rehabilitation period, when directed by a physician and with appropriate programming to the IPG, the patient can initiate at-home use by swiping a magnet over the IPG implant site which activates the IPG to deliver stimulation while rehabilitation movements are performed.

The applicant stated that the ViviStim® Paired VNS System was designated as a Breakthrough Device on February 10, 2021 for use in stimulating the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. According to the applicant, the ViviStim® Paired VNS System received FDA premarket approval on August 27, 2021 as a Class III implantable device for the same indication. The applicant stated that the technology became commercially available on April 29, 2022 due to manufacturing delays.

According to the applicant, there are no unique ICD–10–PCS procedure codes to report the implantation of the device. The applicant noted that together the following two ICD–10–PCS codes describe the insertion of the ViviStim® Paired VNS System: 0JH60BZ (Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach) and 00HE0MZ (Insertion of neurostimulator lead into cranial nerve, open approach). The applicant noted that these codes may be used for any cranial nerve stimulator insertion procedure, including VNS therapy for treatment resistant depression, VNS therapy for refractory epilepsy, and upper airway stimulation to treat obstructive sleep apnea. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify insertion of the ViviStim® Paired VNS System and was granted approval for the following procedure code effective October 1, 2022: X0HQ3R8 (Insertion of neurostimulator lead with paired stimulation system into vagus nerve, percutaneous approach, new technology group 8).

The applicant also provided the ICD–10–CM diagnosis codes in the table that follows. The applicant stated that moderate to severe upper limb impairment is described in the ICD–10–CM as monoplegia (single limb) or hemiplegia (single laterality, including upper limb). The applicant stated that the FY 2021 ICD–10–CM code set [204] includes monoplegia and hemiplegia as a sequela of infarction (stroke), and delineates codes based upon stroke type (hemorrhagic versus ischemic). Therefore, the applicant stated that the ICD–10–CM diagnosis codes in the following table describe chronic moderate to severe upper arm impairment as a sequela of ischemic stroke, and are related to the use of the ViviStim® Paired VNS System.

ICD-10-CM	Description
169.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
169.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
169.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
169.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
169.339	Monoplegia of upper limb following cerebral infarction affecting unspecified side
169.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
169.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
169.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
169.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
169.359	Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side

With respect to the cost criterion, the applicant presented the following analysis. The applicant searched the FY 2019 MedPAR claims data set released with the FY 2022 IPPS/LTCH PPS final rule for cases representing patients who may be eligible for the ViviStim® Paired VNS System. The applicant identified cases reporting the ICD–10–PCS codes 0JH60BZ and 00HE0MZ in combination with one of the ICD–10–CM diagnosis codes, noted previously, describing moderate to severe upper limb impairment. The applicant then mapped the cases to the appropriate MS–DRGs using MS–DRG Grouper Version 39.0. After imputing a case count of 11 for those MS–DRGs with fewer than 11 cases, the applicant identified 285 claims mapping to 12 MS–DRGs, with 65% of cases mapping to MS–DRGs 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC), 041 (Peripheral Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator) and 042 (Peripheral Cranial Nerve and Other Nervous System Procedures without CC/MCC).

The applicant then removed 100% of charges associated with Medical/Surgical Supplies and Devices (prior technology, revenue centers 027X, and 0624). The applicant asserted that the use of the Vivistim® Paired VNS System is expected to replace the majority of existing technologies, although some devices would still be required to perform the procedure. The applicant stated that because it could not determine the estimated percentage of the total charges that would be replaced, it removed 100% of these total charges to be as conservative as possible. The applicant did not remove charges related to the technology being replaced,

[204] *https://www.cms.gov/medicare/icd-10/2021-icd-10-cm*, effective October 1, 2020 through September 30, 2021.

stating that the financial impact of utilizing the Vivistim® Paired VNS System on hospital resources compared to prior technologies other than on Medical Supplies is minimal, and that 100% of charges for Medical/Surgical Supplies had been removed in the previous step.

The applicant standardized the charges by applying the three-year inflation factor of 1.20469 used in the FY 2022 IPPS/LTCH PPS final rule and correction notice to calculate outlier threshold charges (86 FR 45542). The applicant then added charges for the new technology by dividing the cost of the ViviStim® Paired VNS System by the national average CCR for implantable devices which is 0.293 as published in the FY 2022 IPPS/LTCH IPPS final rule (86 FR 44966). The applicant calculated a final inflated average case-weighted standardized charge per case of $200,398 which exceeded the average case-weighted threshold amount of $107,963. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the ViviStim® Paired VNS System meets the cost criterion.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28350), we agreed with the applicant that the ViviStim® Paired VNS System meets the cost criterion and therefore proposed to approve the ViviStim® Paired VNS System for new technology add-on payments for FY 2023.

Based on preliminary information from the applicant at the time of the proposed rule, the total cost of the ViviStim® Paired VNS System to the hospital was $36,000 per patient. According to the applicant, this cost represents the entire per-patient cost of the system to hospital providers—specifically for the cost of the Implantable Pulse Generator and stimulation lead. Per the applicant, there is no charge associated with the external paired stimulation controller and the magnet/take-home patient programmer. The applicant stated that the external paired stimulation controller may be used on multiple patients and that it retains a service agreement with each provider to own, maintain, and update the hardware and software that resides on that device component. The applicant has also stated that they have this service agreement with providers for the magnet/take-home patient programmer. Therefore, as the applicant has stated they retain and maintain the reusable hardware components at no charge to the providers, we stated that it appeared that capital components were not included in the cost of the technology. We welcomed public comment on the cost information provided by the applicant for the purpose of calculating the new technology add-on payment amount.

We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the ViviStim® Paired VNS System would be $23,400 for FY 2023 (that is, 65% of the average cost of the technology).

We invited public comments on whether the ViviStim® Paired VNS System meets the cost criterion and our proposal to approve new technology add-on payments for the ViviStim® Paired VNS System for FY 2023 for use in stimulating the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

Comment: We received a few comments supporting our proposal to approve new technology add-on payments for FY 2023. The applicant also noted that the ViviStim® Paired VNS System received FDA premarket approval on August 27, 2021; however, a manufacturing delay prevented market availability of the device until April 29, 2022. The applicant requested that CMS begin the newness period for the Vivistim® Paired VNS System using the latter market availability date of April 29, 2022. The applicant also supported our proposed maximum new technology add-on payment amount.

Response: We thank the commenters for their support and feedback. We agree that the newness date for this technology is the date on which ViviStim® Paired VNS System became available on the market, April 29, 2022. We note that though, generally, our policy is to begin the newness period on the date of FDA approval or clearance, we may consider a documented delay in the technology's market availability in our determination of newness (77 FR 53348 and 70 FR 47341).

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the ViviStim® Paired VNS System meets the cost criterion. Therefore, we are finalizing our proposal to approve new technology add-on payments for the ViviStim® Paired VNS System for FY 2023, and we consider the beginning of the newness period to commence on April 29, 2022, which is when the technology became commercially available for the indication covered by its Breakthrough Device designation, for use in stimulating the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

Based on the information at the time of this final rule, the cost per case of the ViviStim® Paired VNS System is $36,000. According to the applicant, this cost represents the entire per-patient cost of the system to hospital providers, specifically for the implantable pulse generator and stimulation lead. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the ViviStim® Paired VNS System would be $23,400 for FY 2023 (that is, 65% of the average cost of the technology). Cases involving the use of the ViviStim® Paired VNS System that are eligible for new technology add-on payments will be identified by the ICD–10–PCS procedure code X0HQ3R8 (Insertion of neurostimulator lead with paired stimulation system into vagus nerve, percutaneous approach, new technology group 8).

b. Alternative Pathways for Qualified Infectious Disease Products (QIDPs)

(1) DefenCath™ (Solution of Taurolidine (13.5 mg/mL) and Heparin (1000 USP Units/mL))

CorMedix Inc. submitted an application for new technology add-on payments for DefenCath™ (solution of taurolidine (13.5 mg/mL) and heparin (1000 USP Units/mL)) for FY 2023. The applicant stated that DefenCath™ is a proprietary formulation of taurolidine, a thiadiazinane antimicrobial, and heparin, an anti-coagulant, that is under development for use as catheter lock solution, with the aim of reducing the risk of catheter-related bloodstream infections (CRBI) from in-dwelling catheters in patients undergoing hemodialysis (HD) through a central venous catheter (CVC). According to the applicant, *in vitro* studies of DefenCath™ indicate broad antimicrobial activity against gram-positive and gram-negative bacteria, including antibiotic resistant strains as well as mycobacteria and clinically relevant fungi. The applicant stated that DefenCath™ is available in a single-dose vial, which is sufficient to fill both lumens of the HD catheter, and is instilled into the catheter lumen as a lock solution at the conclusion of each dialysis session and aspirated at the beginning of the next dialysis session. The applicant noted that DefenCath™ cannot be flushed or injected into the patient and that dosing is calibrated to the volume of the catheter lumens.

Per the applicant, DefenCath™ was designated by FDA as a QIDP in 2015 for the prevention of CRBSI in patients with end-stage renal disease (ESRD) receiving HD through a central venous catheter, and has been granted FDA Fast Track status. The applicant indicated that it is pursuing an NDA under FDA's LPAD for the same indication, which the applicant also stated received Priority Review. The applicant noted that FDA issued a Complete Response Letter in 2021 denying the NDA due to concerns with the third-party manufacturing facility. The applicant stated that the NDA has been resubmitted and anticipates approval in the third quarter of CY 2022.[205] We note that, as an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), DefenCath™ is eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2023).

The applicant applied for and received a unique ICD–10–PCS procedure code to identify cases involving the administration of DefenCath™ in 2022. Effective October 1, 2022, DefenCath™ administration can be identified by ICD–10–PCS procedure XY0YX28 (Extracorporeal introduction of taurolidine anti-infective and heparin anticoagulant, new technology group 8).

With regard to the cost criterion, the applicant provided two analyses to demonstrate that DefenCath™ meets the cost criterion. The applicant first searched the FY 2019 MedPAR file released with the FY 2022 IPPS/LTCH PPS final rule for claims based on the presence of one of the following ICD–10–CM diagnosis codes used to identify ESRD, chronic kidney disease (CKD), acute kidney injury (AKI) or acute tubular necrosis (ATN).

ICD-10-CM	Description
N17.0	Acute kidney failure with tubular necrosis
N17.9	Acute kidney failure, unspecified
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
N18.30	Chronic kidney disease, stage 3 unspecified
N18.31	Chronic kidney disease, stage 3a
N18.32	Chronic kidney disease, stage 3b
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N18.9	Chronic kidney disease, unspecified

Per the applicant, DefenCath™ will be used for patients receiving HD through a CVC. The applicant stated that coding to identify this population is difficult because the available CVC codes only describe the insertion of a CVC. The applicant asserted that it is not possible to identify in the MedPAR file those patients who had previously received a CVC and are now hospitalized and receiving HD. Therefore, the applicant developed two sets of selection criteria: claims with codes for HD (Analysis A) and claims with codes for both HD and CVC (Analysis B). The applicant asserted that Analysis A overstates the population of patients eligible for DefenCath™ because it includes any patient receiving HD, regardless of whether a central venous catheter is used. The applicant also asserted that Analysis B undercounts the potential cases because CVC codes are not always available on inpatient claims.

In the first analysis (Analysis A), which included only claims with codes for chronic HD, the applicant searched for claims based on the presence of one of the ICD–10–CM diagnosis codes previously listed and then limited the selection criteria to claims including ICD–10–CM diagnosis code Z49.31 (encounter for adequacy testing for HD)

[205] The statement in the proposed rule (87 FR 28350) that the applicant anticipated approval before July 1, 2022 was in error and has been corrected here.

or one of the following ICD–10–PCS procedure codes for HD:

ICD-10-PCS	Description
5A1D00Z	Performance of urinary filtration, single
5A1D60Z	Performance of urinary filtration, multiple
5A1D70Z	Performance of urinary filtration, intermittent, less than 6 hours per day
5A1D80Z	Performance of urinary filtration, prolonged intermittent, 6 - 18 hours per day
5A1D90Z	Performance of urinary filtration, continuous, greater than 18 hours per day

After imputing a case count of 11 to any MS–DRG with fewer than 11 cases in the FY 2019 MedPAR file released with the FY 2022 IPPS final rule, the applicant identified a total of 490,790 cases mapping to 512 MS–DRGs. The following table shows the top 20 MS–DRGs, which account for 57% of all cases included in Analysis A.

MS-DRG	Description
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC
291	Heart Failure and Shock with MCC
640	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes with MCC
252	Other Vascular Procedures with MCC
314	Other Circulatory System Diagnoses with MCC
682	Renal Failure with MCC
193	Simple Pneumonia and Pleurisy with MCC
377	Gastrointestinal Hemorrhage with MCC
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC
280	Acute Myocardial Infarction, Discharged Alive with MCC
673	Other Kidney and Urinary Tract Procedures with MCC
189	Pulmonary Edema and Respiratory Failure
391	Esophagitis, Gastroenteritis and Miscellaneous Digestive Disorders with MCC
304	Hypertension with MCC
246	Percutaneous Cardiovascular Procedures with Drug-eluting Stent with MCC or 4+ Arteries or Stents
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
308	Cardiac Arrhythmia and Conduction Disorders with MCC
286	Circulatory Disorders Except AMI, with Cardiac Catheterization with MCC
870	Septicemia or Severe Sepsis with MV >96 Hours
637	Diabetes with MCC

For Analysis B, the applicant used the same case selection criteria as Analysis A (the presence of an ICD–10-procedure or diagnosis code for HD only) but further limited cases to those that include one of the following ICD–10 procedure codes for the insertion of a CVC.

ICD-10-PCS	Description
03130ZD	Bypass right subclavian artery to upper arm vein, open approach
0JH60WZ	Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, open approach
0JH60XZ	Insertion of tunneled vascular access device into chest subcutaneous tissue and fascia, open approach
0JH63WZ	Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, percutaneous approach
0JH63XZ	Insertion of tunneled vascular access device into chest subcutaneous tissue and fascia, percutaneous approach
0JHD0WZ	Insertion of totally implantable vascular access device into right upper arm subcutaneous tissue and fascia, open approach
0JHD0XZ	Insertion of tunneled vascular access device into right upper arm subcutaneous tissue and fascia, open approach
0JHD3WZ	Insertion of totally implantable vascular access device into right upper arm subcutaneous tissue and fascia, percutaneous approach
0JHD3XZ	Insertion of tunneled vascular access device into right upper arm subcutaneous tissue and fascia, percutaneous approach
0JHF0WZ	Insertion of totally implantable vascular access device into left upper arm subcutaneous tissue and fascia, open approach
0JHF0XZ	Insertion of tunneled vascular access device into left upper arm subcutaneous tissue and fascia, open approach
0JHF3WZ	Insertion of totally implantable vascular access device into left upper arm subcutaneous tissue and fascia, percutaneous approach
0JHF3XZ	Insertion of tunneled vascular access device into left upper arm subcutaneous tissue and fascia, percutaneous approach
0JHL0WZ	Insertion of totally implantable vascular access device into right upper leg subcutaneous tissue and fascia, open approach
0JHL0XZ	Insertion of tunneled vascular access device into right upper leg subcutaneous tissue and fascia, open approach
0JHL3WZ	Insertion of totally implantable vascular access device into right upper leg subcutaneous tissue and fascia, percutaneous approach
0JHL3XZ	Insertion of tunneled vascular access device into right upper leg subcutaneous tissue and fascia, percutaneous approach
0JHM0WZ	Insertion of totally implantable vascular access device into left upper leg subcutaneous tissue and fascia, open approach
0JHM0XZ	Insertion of tunneled vascular access device into left upper leg subcutaneous tissue and fascia, open approach
0JHM3WZ	Insertion of totally implantable vascular access device into left upper leg subcutaneous tissue and fascia, percutaneous approach
0JHM3XZ	Insertion of tunneled vascular access device into left upper leg subcutaneous tissue and fascia, percutaneous approach

The applicant asserted that the patient population in Analysis B (HD and central venous catheter) is more likely to receive DefenCath™ during an inpatient stay. After imputing a case count of 11 to any MS–DRG with fewer than 11 cases, the applicant identified a total of 60,679 cases mapping to 408 MS–DRGs. The following table shows the top 20 MS–DRGs by case count, which account for 72% of all cases included in Analysis B.

MS-DRG	Description
673	Other Kidney and Urinary Tract Procedures with MCC
314	Other Circulatory System Diagnoses with MCC
871	Septicemia or Severe Sepsis Without MV >96 Hours with MCC
291	Heart Failure and Shock with MCC
252	Other Vascular Procedures with MCC
674	Other Kidney and Urinary Tract Procedures with CC
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC
870	Septicemia or Severe Sepsis with MV >96 Hours
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
264	Other Circulatory System O.R. Procedures
907	Other O.R. Procedures for Injuries with MCC
280	Acute Myocardial Infarction, Discharged Alive with MCC
286	Circulatory Disorders Except Ami, with Cardiac Catheterization with MCC
640	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes with MCC
003	Ecmo or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures
004	Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures
246	Percutaneous Cardiovascular Procedures with Drug-eluting Stent with MCC or 4+ Arteries or Stents
270	Other Major Cardiovascular Procedures with MCC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
377	Gastrointestinal Hemorrhage with MCC

In both analyses, the applicant did not remove charges for prior technology because DefenCath™ would not replace other therapies a patient may receive during an inpatient stay. The applicant standardized the charges using the FY 2022 IPPS final rule impact file and applied a 4-year inflation factor of 1.281834 to update the charges from FY 2019 to FY 2023 based on the inflation factor used to update the outlier threshold in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45542). The applicant did not add charges for new technology as the cost of DefenCath™ has not yet been determined but believes that the technology meets the

cost criterion without the additional charges.

The applicant calculated a final inflated case-weighted average standardized charge per case of $116,221 for Analysis A and a final inflated case-weighted average standardized charge per case of $203,746 for Analysis B. The applicant also determined an average case weighted threshold amount of $77,290 in Scenario A and $96,645 in Scenario B. Because the final inflated case-weighted average standardized charge per case for each scenario exceeded the average case-weighted threshold amount for both scenarios, the applicant asserted that DefenCath™ meets the cost criterion.

In the proposed rule, we agreed that the technology meets the cost criterion and therefore proposed to approve DefenCath™ for new technology add on payments for FY 2023. We stated in the proposed rule that we expected the applicant to submit its cost per case information prior to the final rule, and that we would provide an update regarding the new technology add-on payment amount for the technology in this final rule. We stated that any new technology add-on payment for DefenCath™ would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payments for QIDPs to the lesser of 75% of the average cost of the technology, or 75% of the costs in excess of the MS–DRG payment for the case.

We invited comments on whether DefenCath™ meets the cost criterion and our proposal to approve DefenCath™ for new technology add-on payments for FY 2023.

Comment: The applicant submitted a public comment in support of CMS' proposal to approve new technology add-on payments for FY 2023 for DefenCath™. The applicant requested that CMS correct erroneous information from the proposed rule, stating that the FDA new device approval date is expected later in the third quarter of 2022, rather than by July 1, 2022, as stated in the proposed rule. The applicant also provided the anticipated cost of DefenCath™, which the applicant states is $5,850 to the hospital, per patient.

Response: We appreciate the applicant's support and provision of the cost information. We appreciate the applicant's clarification that the FDA new device approval date is anticipated late in the third quarter of CY 2022 rather than by July 1, 2022 as stated in the proposed rule. This discussion now accurately reflects the anticipated timeline for FDA approval.

Comment: A commenter expressed concern that without information on the cost of DefenCath™ at the time of the publication of the proposed rule, it is difficult to comment positively or negatively on the cost of the technology. This commenter also expressed concern that, without FDA approval at the time of the publication of the proposed rule, it is likewise difficult to comment on the potential impact of the technology. The commenter raised concerns that applicants under the Alternative Pathway for Transformative New Devices and Alternative Pathway for Certain Antimicrobial Products do not have to meet the substantial clinical improvement criterion under 412.87(d) and recommend that CMS incorporate substantial clinical improvement in its evaluation of applicants under the alternative pathways.

Response: We thank the commenter for its input. As discussed in FY 2020 IPPS/LTCH PPS final rule (84 FR 42294 through 42295), we believe that although there may be less certainty of clinical benefit or data representing the Medicare beneficiary population as compared to the evidence standard for substantial clinical improvement under the current new technology add-on payment policy pathway, the benefits of providing early access to critical and life-saving new cures and technologies that improve beneficiary health outcomes support the alternative pathway. We also stated our belief that the evidence base to demonstrate substantial clinical improvement may not be fully developed at the time of FDA marketing authorization. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a further discussion of the development of these alternative pathways.

With respect to cost information, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, we assess the adequacy of the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology by evaluating whether the charges for cases involving the new technology exceed certain threshold amounts. The MS–DRG threshold amounts used in evaluating new technology add-on payment applications for FY 2023 are presented in a data file that is available, along with the other data files associated with the FY 2022 IPPS final rule on the CMS website at: *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-final-rule-home-page*. As discussed in the proposed rule, we agreed that based on the applicant's cost analysis, the final inflated case-weighted average standardized charge per case for the technology exceeded the applicable average case-weighted threshold amount. We also note that applicants for new technology add-on payment are not required to have FDA approval by the time of the publication of the proposed rule. In addition, and as discussed in the proposed rule and later in this final rule, where cost information is not yet available at the time of the proposed rule, we note our expectation is that the applicant will submit cost information prior to the final rule, and indicate that we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe DefenCath™ (a single dose vial, solution of Taurolidine (13.5 mg/mL) and Heparin (1000 USP Units/mL)) meets the cost criterion. Therefore, we are granting a conditional approval for DefenCath™ for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization by July 1, 2023 (that is, by July 1 of the fiscal year for which the applicant applied for new technology add-on payments (2023)). In the proposed rule we stated that as an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), DefenCath™ is eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2023) (87 FR 28350). If DefenCath™ receives FDA marketing authorization before July 1, 2023, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If FDA marketing authorization is received on or after July 1, 2023, no new technology add-on payments will be made for cases involving the use of DefenCath™ for FY 2023.

Based on the information at the time of this final rule, the cost per case of the DefenCath™ is $5,850. Under § 412.88(a)(2) we limit new technology add-on payments for QIDPs to the lesser of 75% of the average cost of the technology, or 75% of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that,

subject to DefenCath™ receiving marketing authorization by July 1, 2023, the maximum new technology add-on payment for a case involving the use of DefenCath™ will be for $4,387.50 for FY 2023 (that is, 75% of the average cost of the technology). Cases involving the use of DefenCath™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XY0YX28 (Extracorporeal introduction of taurolidine anti-infective and heparin anticoagulant, new technology group 8).

c. Other Comments

We received several public comments on new technology add-on payment alternative pathway recommendations that were outside the scope of the proposals included in the FY 2023 IPPS/LTCH PPS proposed rule and we are therefore not addressing them in this final rule. We appreciate these comments and may consider them for possible proposals in future rulemaking.

8. Use of National Drug Codes (NDCs) To Identify Cases Involving Use of Therapeutic Agents Approved for New Technology Add-On Payment

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434 through 49435), as a part of the transition to the ICD–10–CM diagnosis and ICD–10–PCS procedure coding system from the ICD–9–CM coding system, CMS established the use of Section ''X'' New Technology codes within the ICD–10–PCS classification to more specifically identify new technologies or procedures that have historically not been captured through ICD–9–CM codes, or to more precisely describe information on a specific procedure or technology than is found with the other sections of ICD–10–PCS. However, as noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28353 through 28355), CMS continued to receive comments from interested parties, including representatives from hospital associations, software vendors, professional societies, and coding professionals, opposing the continued creation of new ICD–10–PCS (for example, Section X) procedure codes for the purpose of administering the new technology add-on payment for drugs and biologics. Specifically, public comments from the ICD–10 Coordination and Maintenance Committee Meetings have stated that the ICD–10–PCS classification system was not intended to represent unique drugs/therapeutic agents and is not an appropriate code set for this purpose. Commenters explained that, since the implementation of ICD–10, Section X codes have been established for procedures describing the administration of a drug/therapeutic agent, which historically were not typically coded in the inpatient hospital setting. Commenters stated their belief that it was not logical nor should it be expected for hospital coding professionals to seek codes for the administration of drugs within the ICD–10–PCS classification system. In addition, we noted that over the past 3 years, the number of applications for new technology add-on payments has continued to increase, which has subsequently resulted in an increasing number of requests for unique ICD–10–PCS (for example, Section X) procedure codes specifically for the purposes of administering the new technology add-on payments.

As discussed in the proposed rule, the current process of requesting, proposing, finalizing and assigning new ICD–10–PCS procedure codes to identify and describe the administration of drugs involves several steps, as described further in this section, and frequently results in a number of procedure codes that are created unnecessarily when the drug/therapeutic agents do not receive approval for the new technology add-on payments, as the administration of drugs/therapeutic agents is not typically coded in the inpatient hospital setting. Applicants seeking a unique ICD–10–PCS (for example, Section X) procedure code to identify the use of their technology for purposes of new technology add-on payments must complete the code request process prior to learning the outcome of their new technology add-on payment application. This process involves a number of steps, including: gathering relevant information and submitting the ICD–10–PCS code request; developing a slide deck for the ICD–10 Coordination and Maintenance Committee Meeting; and reviewing the background paper draft for the ICD–10 Coordination and Maintenance Committee Meeting agenda and meeting materials. CMS also expends significant time, effort, and resources to administer this process, which is compounded by the increasing number of requests for unique ICD–10–PCS (for example, Section X) procedure codes. CMS must work with applicants to review, prepare, and present the code proposals at ICD–10 Coordination and Maintenance Committee Meetings, then review and summarize public comments received in response to the meetings, and ultimately make a decision on the codes requested for new technology add-on payment policy purposes before the outcome of the new technology add-on payment application (approval or denial) is known. Following the end of the three-year timeframe for which a code was created in connection with a new technology add-on payment application, the disposition of the Section X code is addressed at a later ICD–10 Coordination and Maintenance Committee meeting and CMS subsequently receives public comments that must be reviewed regarding this disposition.

We stated that interested parties had submitted comments that suggested alternative options to the use of Section X procedure codes to identify therapeutic agents for the administration of the new technology add-on payment policy. The majority of commenters supported using National Drug Codes (NDCs), because it would avoid creating duplicate codes within the ICD–10–PCS and NDC code sets to identify the same technology/product, which would allow for predictive and efficient coding. Commenters also stated that using NDCs would generate product data on inpatient claims that would allow for outcomes analyses, thus providing the same benefit as a unique ICD–10–PCS code. Some commenters suggested using the 3E0 Administration Table within the ICD–10–PCS code set, as opposed to Section X, as they stated this would be a more intuitive location for coders to look for ICD–10–PCS procedure codes describing the administration of therapeutic agents. However, a commenter noted that this would be unsustainable due to the potentially large number of new products coming to market. A few commenters also suggested using different drug terminologies, such as RxNorm, in lieu of using Section X codes for the time period needed to administer the new technology add-on payment. We also noted that we have previously established the use of NDCs as an alternative code set for the purposes of administering the new technology add-on payment in circumstances where an ICD–10–PCS code was not available to uniquely identify the use of the technology. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53351 through 53354), we established the use of the NDC code set to identify oral medications where no inpatient procedure was associated, to report the oral administration of the drug DIFICID™. We finalized that the NDC for DIFICID™ would be used in conjunction with an ICD–9–CM diagnosis code to uniquely identify the indication for which administration of the drug (technology) was performed for

new technology add-on payment purposes. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41311), we stated that we believed that the circumstances with respect to the identification of eligible cases reporting the use of VABOMERE™, which was administered by IV infusion, were similar to those addressed in the FY 2013 IPPS/LTCH PPS final rule with regard to DIFICID™ because we also did not have current ICD–10–PCS code(s) to uniquely identify the use of VABOMERE™ to make the new technology add-on payments. Therefore, consistent with our approach in FY 2013, we stated that we would identify cases involving the use of VABOMERE™ that were eligible for FY 2019 new technology add-on payments using its NDCs 65293–0009–01 or 70842–0120–01[206] (VABOMERE™ Meropenem-Vaborbactam Vial). At the time of its new technology add-on payment application approval, VABOMERE™ was not assigned a corresponding ICD–10–PCS procedure or ICD–10–CM diagnosis code along with its NDCs. In addition, cases involving the use of two therapeutic agents that qualify for NCTAP, which is administered similarly to the new technology add-on payment, are identified using the NDCs for these products for the purposes of the NCTAP, because there are not currently ICD–10–PCS procedure codes that uniquely describe the administration of these therapies.[207]

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28353 through 28355), we stated that we believed that our previous policies regarding the use of NDCs to identify the administration of certain therapeutic agents could be consistently applied toward broader future usage of the NDCs to identify therapeutic agents eligible for the new technology add-on payment. Additionally, we stated that we believed that the use of an existing code set to identify therapeutic agents eligible for the new technology add-on payment would address concerns raised by commenters regarding the use of the ICD–10–PCS classification system to identify these agents, and reduce the need for applicants to seek a unique ICD–10–PCS code through the ICD–10–PCS Section X code request process in advance of a determination on their new technology add-on payment applications.

Therefore, as we discussed further in this section of the proposed rule and this final rule, we proposed for FY 2024 to instead use NDCs to identify cases involving the use of therapeutic agents approved for the new technology add-on payment. We stated that we anticipated that this proposal would reduce work for hospital coding professionals in becoming familiar with newly created ICD–10–PCS Section X codes to describe the administration of therapeutic agents and in searching for these codes within the documentation and within the classification in what may be non-intuitive locations. We stated that we also expected that the proposed change would address concerns regarding the creation of duplicative codes within the ICD–10–PCS procedure coding system to describe the administration of therapeutic agents, which would also reduce the need for vendors to incorporate additional procedure codes into their coding products; for educators to provide training on these codes; and for programmers to maintain codes that may be seldom reported on inpatient claims but for the purposes of the new technology add-on payment, in their databases. We stated it would also reduce efforts associated with determining the disposition of procedure codes describing therapeutic agents that have reached the end of their 3-year new technology add-on payment timeframe.

Furthermore, we stated that we believed that NDCs are a viable alternative to Section X codes for the administration of the new technology add-on payment for therapeutic agents. We stated that we believed inpatient hospital staff are familiar with using NDCs, and as stated earlier, we have previously utilized NDCs to administer the new technology add-on payment. However, to allow for adequate time to implement this regular usage of NDCs with the new technology add-on payment for health care providers and hospital coding professionals, we proposed a transitional period for FY 2023. During this transitional period, we proposed to utilize NDCs to identify the administration of therapeutic agents for new technology add-on payment purposes. However, we also proposed to utilize ICD–10–PCS Section X codes, including codes newly created for FY 2023, for therapeutic agents during the FY 2023 new technology add-on payment application cycle. Beginning with the FY 2024 new technology add-on payment application cycle, we proposed to utilize only NDCs to identify claims involving the administration of therapeutic agents approved for the new technology add-on payment, with the exception of claims involving therapeutic agents that are not assigned an NDC by FDA (for example, blood, blood products, etc.) and are approved for the new technology add-on payment. Cases involving the use of these technologies approved for the new technology add-on payment would continue to be identified based on the assigned ICD–10–PCS procedure code. A unique ICD–10–PCS procedure code would also still be needed to identify cases involving the use of CAR T-cell and other immunotherapies that may be assigned to Pre-MDC MS–DRG 018, because the ICD–10 MS–DRG GROUPER logic for assignment to Pre-MDC MS–DRG 018 is comprised of the procedure codes describing these CAR T-cell and other immunotherapy products. Therefore, under the proposal, beginning with FY 2024 new technology add-on payment applications submitted for a therapeutic agent, CMS would review the information and inform the applicant, in advance of the deadline for submitting an ICD–10–PCS procedure code request to the ICD–10 Coordination and Maintenance Committee for consideration at the March meeting, if it would be necessary to submit such a code request for purposes of identifying cases involving the use of the therapeutic agent for the new technology add-on payment, if approved, or if, based on the information made available with the application, the NDC could be used to identify such cases, and therefore, the applicant would not need to submit an ICD–10–PCS procedure code request. For each applicable technology that may be approved for new technology add-on payment, we proposed to indicate the NDC(s) to use to identify cases involving the administration of the therapeutic agent for purposes of the new technology add-on payment.

Specifically, we proposed that, during the transitional period beginning with discharges on or after October 1, 2022 (FY 2023), the administration of therapeutic agents newly approved for new technology add-on payments would be uniquely identified using either their respective NDC(s) or ICD–10–PCS procedure code(s), in combination with ICD–10–CM codes when appropriate. As stated in our FY 2013 IPPS/LTCH PPS final rule, the use of the NDCs ''does not preclude CMS from using additional ICD–9–CM procedure or diagnosis codes to identify cases for this new technology in conjunction with this alternative code

[206] We note that these are not the FDA assigned NDCs, but rather have been converted from 10-digit NDCs assigned by FDA to the HIPAA compliant 11-digit format.

[207] New COVID–19 Treatments Add-On Payment (NCTAP) *https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap.*

set'' (77 FR 53352). Therefore, we stated when necessary, we may require the use of additional ICD–10–PCS procedure and/or ICD–10–CM diagnosis codes to uniquely identify cases using these technologies. We stated that we would continue the use of the existing ICD–10–PCS procedure codes to identify the administration of therapeutic agents previously approved for the new technology add-on payment and that remain eligible for the new technology add-on payment for FY 2023.

We further proposed that, beginning with discharges on or after October 1, 2023 (FY 2024), the administration of therapeutic agents newly approved for the new technology add-on payments beginning FY 2024 or a subsequent fiscal year would be uniquely identified only by their respective NDC(s), along with the corresponding existing ICD–10 code(s) required to uniquely identify the therapeutic agents, when necessary, to make the new technology add-on payments. For technologies that were newly approved for new technology add-on payments for FY 2023 (beginning with discharges on or after October 1, 2022) and remain eligible for the new technology add-on payment for FY 2024 or a subsequent fiscal year, we proposed to continue to allow the use of either the existing ICD–10–PCS procedure codes or NDCs to identify the administration of those therapeutic agents. For technologies that were newly approved for new technology add-on payments prior to FY 2023 and remain eligible for the new technology add-on payment for FY 2024 or a subsequent fiscal year, we stated we would continue to use the existing ICD–10–PCS procedure codes to identify the administration of those therapeutic agents. We invited public comments on our proposal to utilize NDCs to identify claims involving the use of therapeutic agents approved for new technology add-on payments, including any potential concerns regarding adoption of this code set for the identification of therapeutic agents for purposes of new technology add-on payments.

Comment: We received multiple comments related to the proposed policy. A commenter stated that the ICD–10–PCS coding system is not intended to represent unique therapeutic agents and is not an appropriate code set for this purpose. The commenter also stated that ICD–10–PCS codes have often been created unnecessarily because the therapeutic agent was not approved for a new technology add-on payment, and that in the absence of a new technology add-on payment, administration of therapeutic agents is not typically coded in the hospital inpatient setting. The commenter stated that assignment of ICD–10–PCS codes by coding professionals solely for new technology add-on payment purposes, for services that would not otherwise be coded in the inpatient setting, is administratively burdensome. Another commenter mentioned that using FDA's NDCs would allow for superior data capture methods and eliminate manual intervention to complete coding. Another commenter stated that given the likelihood of continued therapeutic innovation, it viewed this proposed policy as a path toward earlier access to these therapies by Medicare beneficiaries. A commenter stated that as hospitals typically capture all NDCs related to a patient stay within their electronic medical record systems, these codes could easily be included with claims. The commenter requested that CMS configure its system to accept all NDC codes, not just those related to products eligible to receive new technology add-on payments, to significantly reduce administrative burden for hospitals.

Several commenters also suggested that if CMS finalizes this policy, we should establish a process to promote and educate hospitals on this policy change to ensure that they are prepared for billing under the new process, including clearly indicating which NDC(s) should be used to identify a particular therapeutic agent for new technology add-on payment purposes, as some therapeutic agents may have more than one applicable NDC. Multiple commenters also urged CMS to extend the proposed transitional process from one year to two years, that is, through FY 2024, with NDC utilization beginning in FY 2025. Some commenters also suggested that during this two-year transition period, CMS should analyze claims data and obtain feedback from interested parties to understand hospitals' usage of NDCs, prior to eliminating the process for using ICD–10–PCS codes.

A commenter expressed support for our proposal to continue use of ICD–10–PCS codes for cases assigned to Pre-MDC MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies) because hospitals may not have had experience with submitting NDCs as part of hospital inpatient claim forms for such cases. Another commenter stated that it was concerned with our proposal to use NDCs in lieu of ICD–10–PCS codes for allogeneic HSCT donor sources because providers, such as hospitals, primarily report ICD–10–PCS codes and are unfamiliar with NDCs for these donor sources. The commenter requested that CMS expand our proposed exceptions to the use of NDCs for therapeutic agents to also include the unique ICD–10–PCS codes describing the infusion of therapeutics that begin with the characters XW1, as well as any future advanced cell therapy donor sources.

A commenter explained that it disagreed with creating individual ICD–10–PCS codes for specific drugs because it believed that ICD–10–PCS nomenclature is for surgical procedures and not specific drugs. The commenter expressed that coders do not routinely assign ICD–10–PCS codes for example, for drugs, radiology procedures, and lab tests, and that this would be an administrative burden on coders, as well as billers, to ensure these drugs are identified through ICD–10–PCS coding. The commenter stated that it would be more cost effective to identify these specific drugs by their NDC number and not an ICD–10–PCS code to ensure adequate reimbursement. Another commenter recommended that CMS reevaluate our proposal to transition to the use of NDCs to identify the administration of a therapeutic agent for purposes of new technology add-on payment because the commenter stated that it would add undue burden on coders who typically do not assign ICD–10–PCS codes for drug administration for inpatient cases. The commenter also requested that CMS pursue broader inpatient claims reporting improvements.

Response: We appreciate the input from the commenters on our proposed use of NDCs to identify cases involving use of therapeutic agents approved for new technology add-on payment and have taken these comments into consideration, as discussed later in this section.

Comment: A couple of commenters were grateful to CMS for listening to feedback from interested parties and putting this proposal forward, but had significant questions about implementation and existing hospital resources for CMS to address prior to finalizing the use of NDCs, and recommended that CMS retain the ICD–10–PCS coding for new technology add-on payments. Other commenters stated that CMS does not currently require NDC reporting on Medicare inpatient claims, except in rare cases of previous new technology add-on payments, and that reporting NDCs for only the occasional drug, and on an inpatient claim, would create new operational burdens for hospitals, especially smaller and rural hospitals, that do not currently have a system for concurrent scanning of NDCs upon administration

of therapeutic agents. Another commenter stated that some hospitals already have systems that would provide an automated method of capturing NDC codes on inpatient claims, but that other facilities, will face new and laborious manual processes despite reporting NDCs on certain outpatient claims. A commenter noted that a recent analysis of hospitals by Deloitte found that incorrect or missing NDC data had caused inaccurate billing.[208] The commenter further stated that it believed the process to educate hospitals and subsequently require the use of NDCs could possibly create a greater administrative burden than it would save. Some commenters also noted that these burdens would come at a time when hospitals continue to address resource and staffing constraints resulting from the COVID–19 PHE. A commenter explained that the transition to NDCs may create complexity in tracking patient cases, which may make it difficult to perform further valuable research on quality of care issues and health outcomes. Another commenter stated that it believed any changes to the current process should be done in a careful manner to ensure that CMS' efforts to move to a more streamlined system do not have any inadvertent implications on claims data.

A commenter stated that because there are multiple proposed exceptions to the use of NDCs, the streamlining and burden reduction of this policy may be limited. Another commenter stated that this proposal would unnecessarily require two separate standards for devices and drugs.

A commenter stated that hospitals are faced with increasingly complex requirements to report drugs to secure reimbursement with variations based upon code sets and patient status. The commenter stated that for inpatient claims there are two ways of reporting drugs for additional payment: hemophilia products reported with HCPCS codes and billed units per date of service (DOS), and new technology add-on payment-eligible drugs reported with a single ICD–10–PCS code independent of number of doses or days administered. The commenter further stated that outpatient claims are reported with HCPCS code and billed units per DOS, with the exception of self-administered oral drugs that were not assigned HCPCS codes, as well as specific new drugs and biologicals billed under the HCPCS Code C9399 (Unclassified drug or biological) and for which the commenter stated that CMS requires that the drug name, dose, amount of waste and NDC number be manually added to the remarks section of the claim. The commenter stated that hospital pharmacy and billing IT systems need remediation with complex maintenance in order to accurately bill drugs based upon the type of drug, whether it is eligible for new technology add-on payment and the status of the patient, and that many hospitals currently do not bill some new technology add-on payment-eligible drugs due to the cumbersome process and amount of the anticipated reimbursement, which the commenter stated could lead to inadvertent billing errors or omissions when a business decision is made that the anticipated payment will be less than the cost to remediate IT systems and maintain these complex billing rules. The commenter further stated that inaccurate data could lead to erroneous future rate-setting by CMS when data is missing from claims. The commenter recommended that CMS instead consider that new technology add-on payment-eligible drugs be billed on inpatient claims with the same instructions as currently used to report hemophilia products, with HCPCS codes and billing units by DOS. The commenter explained that having one way to bill drugs on inpatient and outpatient claims would reduce IT programming expense and reduce errors with increased standardization. The commenter requested that the CMS HCPCS Working Group assign HCPCS codes to items eligible for new technology add-on payment, even if they normally would not be assigned a HCPCS code. The commenter stated that as HCPCS codes are assigned quarterly, this would eliminate the need for special notification if new NDCs are marketed after the implementation of the new technology add-on payment status and before the next rule-making cycle. The commenter further recommended that if CMS were to finalize its proposal to use NDCs, CMS should work with the National Uniform Billing Committee (NUBC) to clarify how 5010 HIPAA transaction standard units of measure and billing quantities should be calculated and reported. The commenter also recommended that CMS work with NUBC to require all payers to accept NDCs on inpatient claims to avoid payer-specific instructions, which require complex and expensive IT programming.

This commenter and several other commenters also requested CMS provide additional information in rulemaking on how NDCs would be utilized: if a NDC may be reported on multiple DOS, or if multi-day therapies must be combined into a single line; whether units of measures and quantities would be required to be reported; if this policy would apply specifically for therapeutic agents eligible for new technology add-on payment or for all therapeutic agents used in Medicare; how a drug product with multiple NDCs would be handled; and how CMS would publish available NDCs for analysis by interested parties and update NDCs if the codes were changed by FDA post-rulemaking.

Several commenters also emphasized the complexity of information transfer from the 10-digit FDA-assigned NDC number format to the 5010 HIPAA transaction standard required 11-digit NDC number format used for billing on claims, especially when trying to reconstitute the NDC back to its FDA standard. Other commenters noted future concerns with potential changes in FDA assignment of NDC numbers from 10-digits to a new 16-digit format, as well as the modifications needed to the 837I/UB–04 forms to accommodate this change.

In addition, commenters highlighted issues regarding a lack of national standards for correctly coding drugs using NDCs, as well as a lack of acceptance of NDCs by all payers, on inpatient claims. A commenter further stated that without specific guidance, current NDC reporting is often inaccurate, resulting in increasing claim rejections for an invalid NDC number. A couple of commenters explained that currently, Form Locator 43 (FL43) on the UB–04 form is not unique to only the NDC number. A commenter stated that they believed that the proposed usage of this field may not be allowed because FL43 is intended for the reporting of NDCs for Medicaid drug rebates, but not for the new technology add-on payment. Some commenters also stated that there was a potential for claim line limits to be reached if multiple NDCs were reported on one claim. These commenters believed that this policy change should be considered as part of broader inpatient claims reporting improvements, with another commenter further stating that grouping together necessary changes to 837I/UB–04 claim forms, alongside updated instructions on NDC reporting for inpatients, would minimize short-term burden as well as data inaccuracies.

Due to these concerns, a few commenters suggested that CMS further

[208] Evaluating Hospital Pharmacy Inventory Management and Revenue Cycle Processes, White Paper Guidance for Healthcare Internal Auditors *https://ahia.org/assets/Uploads/pdfUpload/WhitePapers/EvaluatingHospitalPharmacyInventoryManagementandRevenueCycleProcesses.pdf.*

study the feasibility of this proposed policy change though a Technical Advisory Group (TAG), consisting of industry experts, before finalizing and implementing this policy. A commenter further recommended that other suggestions noted by CMS, such as the 3E0 Administration Table within ICD–10–PCS code set and RxNorm, along with other options, such as the HCPCS code set or a revision to the process that allows the ICD–10–PCS code to be pending assignment until the finalization of the new technology add-on payment determination, should be explored by the TAG and presented in an upcoming proposed rule. Another commenter recommended that CMS address alignment with timing for U.S. implementation of ICD–11 codes.

Response: We appreciate the input from commenters on our proposed use of NDCs to identify cases involving use of therapeutic agents approved for new technology add-on payments. We acknowledge that interested parties have continued to share concerns regarding our current use of the ICD–10–PCS classification system to identify therapeutic agents eligible for new technology add-on payments. As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28353 through 28355), we had anticipated that our proposal to use the NDC, with its previously established use as an alternative code set for the purposes of administering the new technology add-on payment, would reduce work for hospital coding professionals in becoming familiar with newly created ICD–10–PCS Section X codes to describe the administration of therapeutic agents. We had also expected that this proposed change would address concerns regarding the creation of duplicative codes within the ICD–10–PCS procedure coding system, which would also reduce the need for vendors to incorporate additional procedure codes into their coding products; for educators to provide training on these codes; and for programmers to maintain codes that may be seldom reported on inpatient claims but for the purposes of the new technology add-on payment in their databases.

However, as previously summarized, commenters have shared concerns that our proposed use of NDCs for this purpose may impose new administrative burdens to hospitals. For example, commenters indicated that hospital pharmacy and billing IT systems that are not currently required to use NDCs for billing on inpatient Medicare claims may need to use manual processes to report NDCs for the purposes of new technology add-on payments, because they may not have existing automated systems in place.

Furthermore, based on review of comments, it is unclear to us the extent to which hospitals and health care providers would utilize NDCs during a transition period in FY 2023, especially if they believe adding these manual processes may result in inadvertent billing errors for therapeutic agents eligible for new technology add-on payments, which commenters state may be further compounded by staffing shortages due to the COVID–19 pandemic. This may limit our ability to obtain comprehensive feedback from interested parties during the transition period, as suggested by commenters, or perform an analysis of claims data to assess if NDCs are being used, prior to fully transitioning to using NDCs for this purpose.

Therefore, after careful consideration of the concerns raised by commenters, we are not finalizing this proposed policy, and will instead reassess this policy proposal in future rulemaking. We believe that this will allow for adequate time to evaluate and consider the issues raised by commenters. We understand that commenters would be interested in further details on how NDCs would be operationalized for the purposes of any such policy change, along with a process to educate hospitals on these changes to ensure accurate billing throughout a transition period. We appreciate that commenters have raised a number of important questions on our proposal, and we will continue to engage the public in these conversations.

9. Proposal to Publicly Post New Technology Add-On Payment Applications

As noted in section II.F.1.f. of the preamble of this final rule, applicants for new technology add-on payments for new medical services or technologies must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways), along with a significant sample of data to demonstrate the new medical service or technology meets the high-cost threshold (OMB–0938–1347). See section II.F.1.f. of the preamble of this final rule for further details on the data and evidence that can be submitted. We post complete application information and final deadlines for submitting a full application on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech*. We also post on the same website tracking forms completed by each applicant, which include the name of each applicant, name of the technology, and a brief description so that interested parties can identify the new medical services or technologies under review before the annual proposed rule. Additionally, section 1886(d)(5)(K)(viii) of the Act provides for a mechanism for public input before the publication of a proposed rule regarding whether a medical service or technology represents a substantial clinical improvement. Consistent with the Act, we hold an annual Town Hall meeting, typically in December following notice of the meeting in the **Federal Register**.

As set forth in 42 CFR 412.87(e)(1), CMS considers whether a technology meets the criteria for the new technology add-on payment and announces the results as part of its annual updates and changes to the IPPS. Accordingly, in drafting the proposed rule, CMS reviews each new technology add-on payment application it receives under the pathway specified by the applicant at the time of application submission, along with supplemental information[209] obtained from the applicant, information provided at the Town Hall meeting, and comments received in response to the Town Hall meeting. In the proposed rule, CMS summarizes the information contained in the application, including the applicant's explanation of what the technology does, background on the disease process, information about the FDA approval/clearance, and the applicant's assertions and supporting data on how the technology meets the new technology add-on payment criteria under § 412.87. In summarizing this information for inclusion in the proposed rule, CMS restates or paraphrases information contained in the application and attempts to avoid misrepresenting or omitting any of an applicant's claims. CMS also tries to ensure that sufficient information is provided in the proposed rule to facilitate public comments on whether the medical service or technology meets the new technology add-on payment criteria. Currently, however, CMS does not make the applications themselves, as completed by the applicants, publicly available. In addition, CMS generally

[209] For the FY 2023 new technology add-on payment applications, the supplemental information deadline to guarantee inclusion in the IPPS proposed rule was December 17, 2021.

does not take into consideration information that is marked as confidential when determining whether a technology meets the criteria for new technology add-on payments.

We note that in the past, CMS has received requests from the public to access and review the new technology add-on payment applications to further facilitate comment on whether a technology meets the new technology add-on payment criteria. In consideration of this issue, we stated in the proposed rule that we agree that review of the original source information from the applications for new technology add-on payments may help to inform public comment. Further, making this information publicly available may foster greater input from experts in the stakeholder community based on their review of the completed application forms and related materials. Accordingly, as we discuss further in this section of the proposed rule and this final rule, we stated that we believe that providing additional information to the public by publicly posting the applications and certain related materials online may help to further engage the public and foster greater input and insights on the various new medical services and technologies presented annually for consideration for new technology add-on payments.

We stated that we also believe that posting the applications online would reduce the risk that we may inadvertently omit or misrepresent relevant information submitted by applicants, or are perceived as misrepresenting such information, in our summaries in the rules. It also would streamline our evaluation process, including the identification of critical questions in the proposed rule, particularly as the number and complexity of the applications have been increasing over time. That is, by making the applications available to the public online, we would afford more time for CMS to process and analyze the supporting data and evidence rather than reiterate parts of the application in the rule.

Therefore, to increase transparency, enable increased stakeholder engagement, and further improve and streamline our evaluation process, we proposed in the FY 2023 IPPS/LTCH PPS proposed rule to publicly post online future applications for new technology add-on payments. Specifically, beginning with the FY 2024 application cycle, we proposed to post online the completed application forms and certain related materials (for example, attachments, uploaded supportive materials) that we receive from applicants. Additionally, we proposed to post information acquired subsequent to the application submission (for example, comments received after the New Technology Town Hall, updated application information, additional clinical studies, etc.). We proposed that we would not post the cost and volume information the applicant provides in the application form itself or as attached materials, or any material included with the application that the applicant indicates is not releasable to the public because the applicant does not own the copyright or the applicant does not have the appropriate license to make the material available to the public, as further described in the next paragraph. We proposed that we would publicly post the completed application forms and related materials no later than the issuance of the proposed rule, which would afford the public the full public comment period to review the information provided by the applicant in its application.

With respect to copyrighted materials, we proposed that on the application form itself, the applicant would be asked to provide a representation that the applicant owns the copyright or otherwise has the appropriate license to make all the copyrighted material included with its application public with the exception of those materials identified by the applicant as not releasable to the public, as applicable. For any material included with the application that the applicant indicates as copyrighted and/or not otherwise releasable to the public, we proposed that the applicant must either provide a link to where the material can be accessed or provide an abstract or summary of the material that CMS can make public, and CMS will then post that link or abstract or summary online, along with the other posted application materials. We invited comments on this proposal.

Under our current practice, we include in the final rule information on the cost of each technology that is approved for the new technology add-on payment for the purposes of calculating the maximum add-on payment, and information on the anticipated volume of the technology for purposes of the impact analysis. For the proposed rule, specifically for applications submitted under the alternative pathway, our current practice is to propose whether or not to approve the application based on the eligibility criteria for the alternative pathway under 42 CFR 412.87(c) or (d) and, where cost information is available from the applicant, to use this information in proposing a maximum add-on payment amount. Where cost information is not yet available, we note our expectation is that the applicant will submit cost information prior to the final rule, and indicate that we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. We noted that we would continue this same approach with respect to including cost and volume information in the proposed and final rules. However, as noted, under our proposal to post online the new technology add-on payment applications, we would not include cost and volume information for either traditional or alternative pathway applications as part of the application materials that would be posted online.

We noted that at times an applicant may furnish information marked as proprietary or trade secret information along with its application for new technology add-on payments. Currently, the application specifies that data provided in the application or tracking form may be subject to disclosure and instructs the applicant to mark any proprietary or trade secret information so that CMS can attempt, to the extent allowed under Federal law, to keep the information protected from public view.[210] We further stated that this instruction would change under our proposal such that information included in the application, other than cost and volume information, would be made publicly available online through posting of the application. We emphasized that the applicant should not submit as part of its application any such proprietary or trade secret information that it does not want to be made publicly available online. As noted, under our existing practice we stated that we generally do not consider information that is marked as confidential, proprietary, or trade secret when determining whether a technology meets the criteria for new technology add-on payments.

We also stated that this proposal would not change the current timeline or evaluation process for new technology add-on payments, the criteria used to assess applications, or the deadlines for various data submissions. Additionally, we stated that we do not expect added burdens on prospective applicants as a result of this

[210] See new technology add-on payment application included in the FY 2023 New Technology Application Packet, available at: *https://www.cms.gov/files/zip/fy-2023-new-technology-application-packet.zip*; and FY 2023 Tracking Forms, available at: *https://www.cms.gov/files/document/fy-2023-tracking-forms-applicants.pdf*.

proposal since we did not propose to fundamentally change the information collected in the application itself or the supplemental information that would be furnished to support the application. As noted, the aim of the proposed policy change is to increase accuracy, transparency, and efficiency for both CMS and stakeholders.

In connection with the proposal to post the new technology applications online, we stated that we expect we would also make changes to the summaries that appear in the annual proposed and final rules, given that the public would have access to the submitted applications themselves (excluding certain information and materials as described previously), while also continuing to provide sufficient information in the rules to facilitate public comments on whether a medical service or technology meets the new technology add-on payment criteria. Specifically, we stated that we do not anticipate summarizing each entire application in the **Federal Register** as we have in the past, given the expanded and public access to the applications under the proposal. In some instances, such as the discussion of the substantial clinical improvement criterion, we stated that we expect to provide a more concise summary of the evidence or a more targeted discussion of the applicant's claims about how that criterion is met based on the evidence and supporting data (although this may vary depending on the application, new medical service or technology, and the nature of supporting materials provided). We expect that we would continue to generally include, at a high-level, the following information in the proposed and final rules: the technology and applicant name; a description of what the technology does; background on the disease process; the FDA approval/clearance status; and a summary of the applicant's assertions. We also noted we expect to provide more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the newness, cost, and substantial clinical improvement criteria. For example, we would provide a list of the applicant's assertions for whether the technology meets the three sub-criteria under the substantial clinical improvement criterion [211] and a list of the sources of data submitted in support of the assertions, along with references to the application in support of these lists. In the proposed rule, we stated we would also continue to provide discussion of the concerns or issues we identified with respect to applications submitted under the traditional pathway, and for an alternative pathway application, we intend to continue to propose whether to approve or disapprove the application, including noting any concerns we have identified, and, as applicable, the maximum add-on payment amount, where cost information is available. In the final rule, we would continue to provide an explanation of our determination of whether a medical service or technology meets the applicable new technology add-on payment criteria and, for approved technologies, the final add-on payment amounts. We stated that as noted, we believe the proposal to post online the completed application forms and other information described previously would afford greater transparency during the annual rulemaking, for purposes of determining whether a medical service or technology is eligible for new technology add-on payments.

We sought public comment on our proposal to publicly post online the completed application forms and certain related materials and updated application information submitted subsequent to the initial application submission for new technology add-on payments, beginning with applications for FY 2024.

Comment: We received many public comments regarding this policy proposal. Overall, commenters appreciated the agency's aims in making the proposal of fostering greater transparency and public input, while mitigating increased burdens and workloads associated with the rising complexity and number of new technology add-on payment applications submitted annually. A few commenters were fully supportive of our proposal, while a majority of the remaining commenters supported the proposal, while suggesting modifications to address concerns about the disclosure of certain information. In particular, these commenters were encouraged by CMS' proposal not to include cost and volume information as part of the application materials that would be posted online, but stated that the proposal did not go far enough to protect potentially confidential, commercially sensitive information (for example, biologics license applications (BLA) or nonpublic studies), and recommended that CMS modify the proposal, offering suggestions for ensuring that such information not be posted online.

Some commenters requested that CMS bifurcate the application to allow a section for information that would not be posted online, afford applicants the opportunity to submit a separate file of confidential information, or allow information in the application to be redacted. Other commenters requested that CMS continue the practice of allowing the applicant to mark sensitive proprietary or trade secret information as confidential and not for posting online. Commenters stated that if the full application were posted online, applicants may refrain from submitting certain information necessary to support the application and meet the new technology add-on payment criteria (for example, clinical information cited but not yet in the public domain and prior to FDA approval and information concerning newness, such as engineering specifics), resulting in applications that are less complete or robust, and therefore, would compromise the goals of the new technology add-on payment process. Absent protection of this information, commenters stated that applicants could apply only after FDA approval, creating significant delays in new technology add-on payment approvals and subsequent beneficiary access.

Commenters also acknowledged that CMS generally does not consider confidential or proprietary information in making a determination whether a new technology meets the new technology add-on payment criteria, but believed there could be circumstances where such information could contribute to the agency's overall understanding of a technology, therapeutic area, or other relevant question that arises during its review (for example, pre-publication study results, which are kept from public release pending their publication in peer-reviewed scientific publications). Another commenter asserted that such data can help CMS better understand the technology and make a more informed decision about the application. The commenters also stated that, without protection of such information, companies would no longer be able to submit such studies until after publication. Commenters also stated that the proposed policy puts the onus on the applicant to not submit this type of information without recognizing that a comprehensive application might require such information.

Additionally, commenters were generally supportive of our proposal regarding copyrighted material.

[211] Sub-criteria referenced are those listed in Question 36 of the new technology add-on payment application, specifically Questions 36a–36c.

Response: We appreciate the support for our proposal and our efforts toward greater transparency, public input, and streamlining of the new technology add-on application process. In making our proposal, we indicated that applicants should not submit proprietary or trade secret information with the application, to avoid such information being posted online as part of the application. Moreover, we proposed not to continue our practice of allowing applicants to mark such information to be withheld from disclosure given that our general policy is not to consider information that is marked confidential, proprietary, or trade secret when determining whether a technology meets the criteria for new technology add-on payments and given the need for the public to understand the information we are relying on in making such decisions. However, in consideration of public comments, we will provide a mechanism for applicants to submit confidential information, including proprietary or trade secret information, that will not be posted online. We anticipate providing a section on the application where applicants can submit confidential information separately from non-confidential information, or otherwise marking sections or questions in the application for which we will not post the information online. Applicants would still be required to submit cost and volume information in the application since this information is necessary; however, we will indicate in the application that cost and volume information will not be publicly posted but certain cost and volume information may still be summarized and discussed in the proposed rule, as is consistent with our current practice. Applicants should expect that, unless otherwise noted in the application that certain information will not be posted publicly (for example, contact information), everything else may be posted publicly. We emphasize that it is the applicant's responsibility to put confidential information only in the areas of the application designated for confidential information and not elsewhere in the application. However, as previously noted, applicants should consider what they include in a confidential section of the application given that we generally do not consider any information that cannot be made public when determining whether a technology meets the new technology add-on payment criteria. With respect to copyrighted information, we are finalizing our proposal without modification.

Additionally, we note that in the past we have received applications in which all the data and information in an application are marked as proprietary or confidential, or where certain information provided in support of the applicant's assertions regarding eligibility for the new technology add-on payment, for example a claim of substantial clinical improvement, is marked as such. In such cases, we reiterate that we generally will not be able to consider that data and information when determining whether a technology meets the criteria for new technology add-on payments. Our process provides for public input, so it is important that we provide the information needed for the public to meaningfully comment on the new technology add-on payment applications, including the applicants' assertions as to why a technology meets the new technology add-on payment criteria.

Comment: A commenter suggested that CMS further study ways to improve and streamline the annual review process. Another commenter requested that CMS defer a decision until the FY 2025 application cycle, allowing more time for interested parties and the agency to more thoroughly consider the implications and potential options to improve the efficiency and capacity of the review process.

Response: As we stated in the proposed rule, we proposed to publicly post online applications for new technology add-on payments to increase transparency, enable increased engagement with interested parties, and improve and streamline our evaluation process. Through this policy, we also are attempting to address some of the downsides and challenges of our current practice of summarizing the contents of the applications by restating or paraphrasing information, ensuring that sufficient information is provided in the proposed rule, and avoiding misrepresenting or omitting any of the applicants' claims. Posting the application and certain related materials online, subject to certain exceptions as discussed in this section, is a straightforward solution and strikes a balance between affording greater transparency and streamlining the application process. Given the reasons we have noted previously, the overall support for the proposal, and after considering the other feedback and suggestions by commenters, we are finalizing our proposal to post applications online, but as previously discussed, we will provide a mechanism for applicants to submit confidential information that would not be included as part of the application materials posted online. We also continue to welcome feedback on the application and review process, including potential options for improving the efficiency and capacity of this process, and we will continue to consider this issue.

Comment: A few commenters raised concerns about the timing of when applications would be posted online. A commenter questioned whether the agency planned to post all applications and related materials online at the same time, or on a rolling basis as they are received and deemed complete, noting that the specific timing of online posting would be highly relevant to applicants given that under the current process, applicants have the opportunity to amend or withdraw an application prior to presentation at the New Technology Town Hall or issuance of the proposed rule. The commenter believed that any new online posting process should preserve an applicant's ability to withdraw an application prior to posting, noting that many applicants submit materials before certainty that the technology meets the criteria for a new technology add-on payment, and with an intent to either supplement or withdraw the application during the cycle, because the annual application cycle often requires a submission well in advance of market introduction. Another commenter noted the fluidity and frequent updates of the data collection process in these applications, which may occur more quickly than the public notice and comment period and therefore, the information made available by CMS may not be current when it is released.

Response: We agree with the commenter that additional information related to the application may be submitted up until the release of the proposed rule and understand that posting the complete application and supplemental information all at once is preferable to continually updating the application information online. Accordingly, we are clarifying that under the final policy we are adopting, we will publicly post the application and any additional information received (with the exception of certain confidential, cost and volume, or copyrighted information as explained previously) at the time the proposed rule is published and no sooner. With regard to the commenter's concern about an applicant's ability to withdraw applications during the application process, we clarify that the policy we are finalizing would not change an applicant's ability to withdraw its application prior to the proposed rule being published and, in such cases, we

would not post those applications online or address them in the proposed rule. In instances, however, where the applicant withdraws its application from consideration after the proposed rule is issued, the application would remain posted online (that is, corresponding to the published discussion of the application in the proposed rule).

After considering the comments, and for the reasons discussed, we are finalizing our proposal to publicly post online new technology add-on payment applications, including the completed application forms, certain related materials (as described previously), and any additional updated application information submitted subsequent to the initial application submission (except certain volume, cost and other information identified by the applicant as confidential), beginning with the application cycle for FY 2024, at the time the proposed rule is published. We are finalizing as proposed our proposal with respect to the treatment of copyrighted information. We are finalizing a modification to our proposal to provide a mechanism for applicants to submit confidential information that would not be posted online, such as in a separate section of the application, or by identifying particular questions for which the information submitted would not be publicly posted. We will not publicly post cost and volume information; however, consistent with our current practice, we will continue to summarize and discuss certain cost and volume information for the proposed rule and will indicate as such in the application. With the exception of information included in a confidential information section of the application, cost and volume information, and materials identified by the applicant as copyrighted and/or not otherwise releasable to the public, the contents of the application and related materials may be posted publicly. We further clarify that we will post these application materials at the time of the proposed rule and no sooner, and that we will not post applications that are withdrawn prior to publication of the proposed rule.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2023 hospital wage index based on the statistical areas appears under section III.A.2. of the preamble of this final rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, IV. The OMB control number for this information collection request is 0938–0050, which expired on March 31, 2022. A 30-day **Federal Register** notice published on June 22, 2022 (87 FR 37338) for the reinstatement of the information collection request. The comment period closed July 22, 2022. Section 1886(d)(3)(E) of the Act also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment for FY 2023 is discussed in section II.B. of the Addendum to this final rule.

As discussed in section III.I. of the preamble of this final rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2023 is discussed in section II.A.4.b. of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. (The OMB control number for approved collection of this information is 0938–0907, which expires on October 31, 2022. An extension of the information collection request is currently being developed. The public will have an opportunity to review and submit comments regarding the extension of this PRA package through a public notice and comment period separate from this rulemaking.) A discussion of the occupational mix adjustment that we are applying to the FY 2023 wage index appears under sections III.E. and F. of the preamble of this final rule.

2. Core-Based Statistical Areas (CBSAs) for the FY 2023 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010, **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963 and 49973 through 49982)) for a full discussion of our implementation of the OMB statistical area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012, and July 1, 2013. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted the updates set forth in OMB Bulletin No. 15–01 effective

October 1, 2016, beginning with the FY 2017 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2017 IPPS/LTCH PPS final rule. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we continued to use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin No. 15–01 specified in the FY 2017 IPPS/LTCH PPS final rule.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to statistical areas since July 15, 2015, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41363), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2018, beginning with the FY 2019 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 17–01, we refer readers to the FY 2019 IPPS/LTCH PPS final rule. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42300 through 42301), we continued to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01.

On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017, OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. Historically OMB bulletins issued between decennial censuses have only contained minor modifications to CBSA delineations based on changes in population counts. However, OMB's 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates created a larger mid-decade redelineation that takes into account commuting data from the American Commuting Survey. As a result, the September 14, 2018, OMB Bulletin No. 18–04 included more modifications to the CBSAs than are typical for OMB bulletins issued between decennial censuses.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) we adopted the updates set forth in OMB Bulletin No. 18–04 effective October 1, 2020, beginning with the FY 2021 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 18–04, we refer readers to the FY 2021 IPPS/LTCH PPS final rule.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017, and July 1, 2018. After reviewing OMB Bulletin No. 20–01, we determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare wage index for FY 2022. While we adopted the updates set forth in OMB Bulletin No. 20–01 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45163 through 45164) consistent with our general policy of adopting OMB delineation updates, we also noted that specific wage index updates would not be necessary for FY 2022 as a result of adopting these updates. In other words, the updates set forth in OMB Bulletin No. 20–01 would not affect any hospital's geographic area for purposes of the wage index calculation for FY 2022. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 20–01, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45163 through 45164).

For FY 2023, we are continuing to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01, 17–01, 18–04 and 20–01.

In connection with our adoption in FY 2021 of the updates in OMB Bulletin 18–04, we adopted a policy to place a 5-percent cap, for FY 2021, on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755) for a complete discussion of this transition. As finalized in the FY 2021 IPPS/LTCH PPS final rule, this transition was set to expire at the end of FY 2021. However, given the unprecedented nature of the ongoing COVID–19 public health emergency (PHE), we adopted a policy in the FY 2022 IPPS/LTCH PPS final rule to apply an extended transition to the FY 2022 wage index for hospitals that received the transition in FY 2021. Specifically, we continued a wage index transition for FY 2022 (for hospitals that received the transition in FY 2021) under which we applied a 5 percent cap on any decrease in the hospital's wage index compared to its wage index for FY 2021 to mitigate significant negative impacts of, and provide additional time for hospitals to adapt to, the CMS decision to adopt the revised OMB delineations. We also applied a budget neutrality adjustment to the standardized amount so that our transition in FY 2022 was implemented in a budget neutral manner under our authority in section 1886(d)(5)(I) of the Act. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (85 FR 45164 through 45165) for a complete discussion of this transition. We also refer readers to section III.N. of the preamble of this final rule which discusses our permanent policy to apply a 5-percent cap on any decrease in a hospital's wage index compared to its wage index from the prior fiscal year.

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. There are two different lists of codes associated with counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the hospital wage index. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we have learned that SSA county codes are no longer being maintained and updated. However, the FIPS codes continue to be maintained by the U.S. Census Bureau. We believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2020. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the

website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html*. We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to discontinue the use of the SSA county codes and began using only the FIPS county codes for purposes of cross walking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates, which were effective October 1, 2017, beginning with the FY 2018 wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. We refer the reader to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130) for a complete discussion of our adoption of FIPS county codes.

Based on the latest information included in the Census Bureau's website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.2010.html*, the Census Bureau has made the following updates to the FIPS codes for counties or county equivalent entities:

- Chugach Census Area, AK (FIPS State County Code 02–063) and Copper River Census Area, AK (FIPS State County Code 02–066), were created from former Valdez-Cordova Census Area (02–261) which was located in CBSA 02. The CBSA code for these two new county equivalents remains 02.

We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS. In addition, we believe that using the latest FIPS codes allows us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. Therefore, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28359), we proposed to implement these FIPS code updates listed previously, effective October 1, 2022, beginning with the FY 2023 wage indexes. We proposed to use these update changes to calculate area wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule (69 FR 49026 through 49034) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963). We note that while the county update changes listed previously changed the county names, the CBSAs to which these counties map did not change from the prior counties. Therefore, we stated that there would be no impact or change to hospitals in these counties for purposes of the hospital wage index as a result of our implementation of these FIPS code updates. We invited public comments on our proposals.

We did not receive any public comments on our proposals. Therefore, for the reasons discussed earlier, we are finalizing our proposal, without modification, to implement the FIPS code updates listed previously, effective October 1, 2022, beginning with the FY 2023 wage indexes. As we proposed, we will use these update changes to calculate the area wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. For FY 2023, Tables 2 and 3 associated with this final rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect these FIPS code updates.

B. Worksheet S–3 Wage Data for the FY 2023 Wage Index

The FY 2023 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2019 (the FY 2022 wage indexes were based on data from cost reporting periods beginning during FY 2018).

1. Included Categories of Costs

The FY 2023 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty).
- Home office costs and hours.
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)).
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590) and modified in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49505 through 49508)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2022, the wage index for FY 2023 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2023 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally Qualified Health Centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers. We did not receive any comments on the discussion in this section.

C. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2023 wage index were obtained from Worksheet S–

3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 for cost reporting periods beginning on or after October 1, 2018, and before October 1, 2019. (As noted in section III.A.1 of the preamble of this final rule, the OMB control number for this information collection request is 0938–0050, which expired on March 31, 2022. A 30-day **Federal Register** notice published on June 22, 2022 (87 FR 37338) for the reinstatement of the information collection request. The comment period closed July 22, 2022). For wage index purposes, we refer to cost reports beginning on or after October 1, 2018, and before October 1, 2019 as the ''FY 2019 cost report,'' the ''FY 2019 wage data,'' or the ''FY 2019 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the FY 2023 wage index includes FY 2019 data submitted to us as of the end of June 2022. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

Consistent with the IPPS and LTCH PPS ratesettings, our policy principles with regard to the wage index include generally using the most current data and information available which is usually data on a 4-year lag (for example, for the FY 2022 wage index we used cost report data from FY 2018) . In section I.F. of the preamble of this final rule, we discuss our analysis of the best available data for use in the development of this FY 2023 IPPS/LTCH PPS final rule given the potential impact of the public health emergency (PHE) for the Coronavirus Disease (COVID–19). For the FY 2023 wage index, the best available data typically would be from the FY 2019 wage data. Our review and analysis of the FY 2019 wage data shows that the data is not significantly impacted by COVID–19 PHE. A comparison of providers shows similar trends in those with cost reports ending during the PHE as compared to providers without cost reports ending during the PHE. The data also shows that changes in the average hourly wage (AHW) for providers were consistent between providers with cost reports ending during the PHE as compared to providers without cost reports ending during the PHE. It appears that the overall impact of the COVID–19 PHE on the FY 2019 wage data has been minimal. Additionally, the changes in the wage data from FY 2018 to FY 2019 show similar trends in the change of the data from FY 2017 to FY 2018. Therefore, we proposed to use the FY 2019 wage data for the FY 2023 wage index.

Comment: A commenter expressed concern that the review and analysis of the FY 2019 wage data with regard to the impact by COVID–19 PHE was unclear. The commenter noted that the proposed rule did not reference tables or files for the public to review to confirm the agency's conclusion. The commenter also stated that it is confusing why CMS stated that the FY 2019 wage data was not impacted by the PHE given that the PHE did not begin until March 2020. The commenter encouraged CMS to share source information so stakeholders can better understand the agency's position, particularly given the review of data suggests that the cost of staffing has increased substantially.

Response: With regard to the commenter that stated that the PHE did not begin until March 2020, we note that the PHE was declared on January 31, 2020 in response to COVID–19. We also note that in March 2020, the World Health Organization declared the COVID–19 outbreak a pandemic.

As previously stated, our review and analysis of the FY 2019 wage data shows that the data is not significantly impacted by COVID–19 PHE. We use the latest audited data to calculate the wage index. The latest audited data as of the FY 2023 rulemaking cycle is cost reports with a begin date during FY 2019. Because we use audited cost report data with a begin date in FY 2019 (on or after Oct 1, 2018 through on or before September 30, 2019), the latest cost report with a begin date in FY 2019 would be September 30, 2019 which would end typically 12 months later on September 30, 2020 (which would include some months in the PHE). The earlier the cost report begin date the less months of data are included in the period of the PHE. As noted in this section of this rule, there are 3,136 providers included in the wage index for FY 2023.

Approximately 1,300 hospitals have cost report data from FY 2019 that has some months of data touching the PHE in the period of January 31, 2020 through September 30, 2020. We note, while the PHE was declared January 31, 2020, the impact of the PHE began to be felt by hospitals beginning in March 2020 (which is re-enforced by the commenter that stated its belief that the PHE began in March 2020). Of these 1,300 hospitals:

- Approximately 80 hospitals have a cost reporting period of 04/01/2019 through 03/30/2020 (one month of data in the period between March 2020 through September 2020).
- Approximately 1,000 hospitals have a cost reporting period of 07/01/2019 through 06/30/2020 (four months of data in the period between March 2020 through September 2020).
- Approximately 85 hospitals have a cost reporting period of 09/01/2019 through 08/30/2020 (six months of data in the period between April 2020 through September 2020).

Based on the previous, approximately 37 percent of hospitals include data from the period of March 2020 through September 2020. The majority of these hospitals (1,000) have a cost report begin date of July 1, 2019 which accounts for approximately 32 percent of all hospitals cost report data; also, the majority of the cost report data for these hospitals (8 months) is not impacted by the PHE. Therefore, the overwhelming majority of hospitals data has no data from the period of March 2020 through September 2020. While some cost reports included some months of data from the period of March 2020 through September 2020, as previously stated, the data shows that changes in the average hourly wage (AHW) for providers were consistent between providers with cost reports ending during the PHE as compared to providers without cost reports ending during the PHE. Additionally, the changes in the wage data from FY 2018 to FY 2019 show similar trends in the change of the data from FY 2017 to FY 2018. We also note, AHW data by provider and CBSA is readily available in our Public Use Files released with each proposed and final rule each fiscal year. Therefore, any comparisons that CMS made within the current year data and prior year data can easily be replicated by the public. We did not receive any comments questioning whether certain providers or CBSAs AHW were grossly affected by the PHE. Therefore, we continue to believe that the data shows that changes in the average hourly wage (AHW) for providers were consistent between providers with cost reports ending during the PHE as compared to providers without cost reports ending during the PHE.

We also note, in section G.2.c. of Appendix A of the FY 2023 IPPS/LTCH proposed rule (87 FR 28709), we provided a table showing the projected impact of proposed changes in the area wage index values for urban and rural hospitals. Specifically, the table compares the shifts in wage index values for hospitals due to proposed changes in the average hourly wage data

for FY 2023 relative to FY 2022. We refer the commenter to this table as well as a similar table that is published in section G.2.c. of Appendix A in this final rule.

Finally, CMS will be looking at the differential effects of the COVID–19 PHE on the audited wage data in future fiscal years. We plan to review the audited wage data, and the impacts of the COVID–19 PHE on such data and evaluate these data for future rulemaking.

We requested that our MACs revise or verify data elements that result in specific edit failures. For the proposed FY 2023 wage index, we identified and excluded 86 providers with aberrant data that should not be included in the wage index. However, we stated that if data elements for some of these providers are corrected, we intended to include data from those providers in the final FY 2023 wage index. We also adjusted certain aberrant data and included these data in the wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than March 19, 2022. For the final FY 2023 wage index, we restored the data of 23 hospitals to the wage index because their data was either verified or improved, and removed the data of 0 hospitals for the first time after the proposed rule due to its data being aberrant. We also restored the data of one provider that we inadvertently excluded from the proposed rule that was not on the delete list in the proposed rule public use file. Thus, 63 hospitals with aberrant data remain excluded from the FY 2023 wage index (86 − 23 = 63).

In constructing the proposed FY 2023 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2019, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We stated in the proposed rule (87 FR 28630 through 28632) that we believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index. For the proposed FY 2023 wage index, we removed 3 hospitals that converted to CAH status on or after January 24, 2021, the cut-off date for CAH exclusion from the FY 2022 wage index, and through and including January 21, 2022, the cut-off date for CAH exclusion from the FY 2023 wage index. Since the proposed rule, we learned of 0 more hospitals that converted to CAH status on or after January 24, 2021, and through and including January 21, 2022, the cut-off date for CAH exclusion from the FY 2023 wage index, for a total of 3 hospitals that were removed from the FY 2023 wage index due to conversion to CAH status. In summary, we calculated the FY 2023 wage index using the Worksheet S–3, Parts II and III wage data of 3,136 hospitals.

For the FY 2023 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the FY 2023 wage index associated with this final rule (available via the internet on the CMS website), includes separate wage data for the campuses of 26 multicampus hospitals. The following chart lists the multicampus hospitals by CSA certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

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CCN of Multicampus Hospital	Full-Time Equivalent (FTE) Percentages
050121	0.86
05B121	0.14
070010	0.96
07B010	0.04
070022	0.99
07B022	0.01
070033	0.93
07B033	0.07
100029	0.53
10B029	0.47
100167	0.56
10B167	0.44
140010	0.82
14B010	0.18
220074	0.89
22B074	0.11
310069	0.82
31B069	0.18
310108	0.97
31B108	0.03
330195	0.89
33B195	0.11

CCN of Multicampus Hospital	Full-Time Equivalent (FTE) Percentages
330103	0.67
33B103	0.33
330214	0.74
33B214	0.26
330234	0.78
33B234	0.22
340115	0.95
34B115	0.05
360020	0.96
36B020	0.04
390006	0.96
39B006	0.04
390115	0.86
39B115	0.14
390142	0.84
39B142	0.16
450033	0.99
45B033	0.01
450330	0.96
45B330	0.04
460051	0.78
46B051	0.22
510022	0.94
51B022	0.06
520009	0.69
52B009	0.31
670062	0.69
67B062	0.31
670107	0.69
67B107	0.31

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We noted that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other, variable, digits in the CCN.

Comment: Commenters opposed the exclusion of hospitals' wage data. These commenters stated that excluding accurate and verified data is inconsistent with the extensive process established by CMS to ensure the accuracy and reliability of hospital wage index data. Commenters also raised concerns about the lawfulness of excluding wage data for these hospitals, stating that section 1886(d)(3)(E) of the Act does not provide the authority for CMS to delete accurately-reported wage data, and doing so is arbitrary and capricious.

Specifically, a commenter opposed the exclusion of hospitals' wage data where hospitals timely submitted corrections or appeals. The commenter stated that where hospitals have available timely-submitted, corrected and verifiable data CMS is obligated to use such data in the wage index calculation. The commenter also stated that there is no statute or regulation authorizing CMS to exclude hospital data based on a unilateral determination that the data is aberrant.

Response: We responded to similar comments in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45168 through 45169). Section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. As previously stated in those final rules in response to similar comments, we believe that, under this section of the

Act, we have discretion to exclude aberrant hospital data from the wage index PUFs to help ensure that the costs attributable to wages and wage-related costs in fact reflect the relative hospital wage level in the hospitals' geographic area. We refer commenters to our previous responses to comments at the **Federal Register** pages cited earlier in this response with regard to the exclusion of hospitals' wage data from the wage index.

Comment: Some commenters urged CMS to lessen the lag of four years in hospitals' cost report data used for the wage index (for example, FY 2019 cost report data used for the FY 2023 wage index) and to consider alternate methods to collect more accurate data.

Another commenter stated that CMS should offer short-term assistance to the hospital community, considering inflationary updates to the wage index as necessary to preserve current service levels, which the commenter believes is a particular risk point for underserved populations. The commenter recommended a more time-sensitive and layered approach to wage index updates to account for excess labor costs driven by increased contract labor and reimbursement rates to preserve our critical national hospital system infrastructure. The commenter stated that CMS could accomplish this by leveraging current Medicare cost report surveys to develop a wage adjustment until the labor market stabilizes. This approach would account for regional disparities and impact, use known and accepted survey data, create a standardized and auditable system, and support hospitals without disrupting the baseline Medicare wage index.

Response: CMS used the most recent audited surveys and data to develop the FY 2023 wage index. We are unclear what alternative data or which current surveys and reporting the commenters are referring to. We note, audited cost report data from FY 2020 will be used for FY 2024 and is not available at the time of this final rule. Therefore, we are unable to account for regional differences without audited data. Also, as previously noted, section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. Uniformly adjusting the salaries and hours for all areas (which is used to calculate an areas AHW) would lead to a commensurate change to the national AHW and not the wage index itself. This is because the wage index is required to be a relative measure. Further, we refer the commenter to the discussion on the market basket in section V. A. 1. of the preamble of this final rule for which we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy (including the more recent historical CPI growth, impacts of the Russia/Ukraine war, current expectations regarding changes to Federal Reserve interest rates, and tight labor markets). Additionally, we note that section 1886(d)(3)(E)(i) of the Act requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments under section 1886(d) are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. Therefore, since the wage index is subject to budget neutrality, any increases or decreases as a result of the data from one FY to the next FY would be implemented in a budget neutral manner.

D. Method for Computing the FY 2023 Unadjusted Wage Index

As stated in the proposed rule (87 FR 28362 through 28365), the method used to compute the FY 2023 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2021 IPPS/LTCH PPS final rule (see 85 FR 58758 through 58761, September 18, 2020), and we did not propose any changes to this methodology. We have restated our methodology in this section of this final rule.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the wage index (in this case, for FY 2023, these were data from cost reports for cost reporting periods beginning on or after October 1, 2018, and before October 1, 2019). In addition, we included data from some hospitals that had cost reporting periods beginning before October 2018 and reported a cost reporting period covering all of FY 2019. These data were included because no other data from these hospitals would be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2019 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2019 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2018, and before October 1, 2019), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35.) In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, and 15, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4. The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52).

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. The formula for Total Hours (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula: (Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35)—(Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43). We then compute the amounts of overhead salaries and hours to be allocated to the excluded areas by multiplying the previously discussed ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to the excluded areas using three steps:

- We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following: (Lines 26 through 43—Lines 28, 33 and 35)/ ((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − (Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).
- We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.
- We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2018, through April 15, 2020, for private industry hospital workers from the Bureau of Labor Statistics' (BLS') Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose to make any changes to the usage of the ECI for FY 2023. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in this rule.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSA's wage index would be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and 42306, August 16, 2019). We stated that we believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a

statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the FY 2023 wage index, we note there is one urban CBSA for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website) which contains the area wage indexes, we include a footnote to indicate to which CBSAs this policy applies. These CBSAs' wage indexes would be equal to total urban salaries plus wage-related costs (from Step 5) in the respective State, divided by the total urban hours (from Step 4) in the respective State, divided by the national average hourly wage (from Step 8) (see 84 FR 42305 and 42306, August 16, 2019). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded, as discussed in this section of this rule.

We refer readers to section II. of the Appendix of the final rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 listed in section VI. of the Addendum to the final rule and available via the internet on the CMS website.

Following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306, August 16, 2019). For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we use such data ''as is,'' and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2018, through April 15, 2020, for private industry hospital workers from the BLS' *Compensation and Working Conditions*. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose any changes to the usage of the ECI for FY 2023. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2018	11/15/2018	1.03404
11/14/2018	12/15/2018	1.03168
12/14/2018	01/15/2019	1.02929
01/14/2019	02/15/2019	1.02694
02/14/2019	03/15/2019	1.02462
03/14/2019	04/15/2019	1.02237
04/14/2019	05/15/2019	1.02026
05/14/2019	06/15/2019	1.01826
06/14/2019	07/15/2019	1.01630
07/14/2019	08/15/2019	1.01429
08/14/2019	09/15/2019	1.01223
09/14/2019	10/15/2019	1.01015
10/14/2019	11/15/2019	1.00808
11/14/2019	12/15/2019	1.00601
12/14/2019	01/15/2020	1.00397
01/14/2020	02/15/2020	1.00196
02/14/2020	03/15/2020	1.00000
03/14/2020	04/15/2020	0.99808

For example, the midpoint of a cost reporting period beginning January 1, 2019, and ending December 31, 2019, is June 30, 2019. An adjustment factor of 1.01630 was applied to the wages of a hospital with such a cost reporting period.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2023, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the methodology, as previously discussed, we stated in the proposed rule (87 FR 28365) that the proposed FY 2023 unadjusted national average hourly wage was $47.77.

We did not receive any comments regarding the discussion of our method for computing the FY 2023 unadjusted wage index. Based on the previously described methodology, the final FY 2023 unadjusted national average hourly wage is the following:

Final FY 2023 Unadjusted National Average Hourly Wage	$47.79

E. Occupational Mix Adjustment to the FY 2023 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2019 Medicare Wage Index Occupational Mix Survey for the FY 2023 Wage Index

Section 304(c) of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25402 through 25403) and final rule (86 FR 45173), we collected data in 2019 to compute the occupational mix adjustment for the FY 2022, FY 2023, and FY 2024 wage indexes. The FY 2023 occupational mix adjustment is based on the calendar year (CY) 2019 survey. Hospitals were required to submit their completed 2019 surveys (Form CMS–10079, OMB Number 0938–0907, expiration date October 31, 2022) to their MACs by September 3, 2020. It should be noted that this collection of information was approved under OMB control number 0938–0907 with an expiration date of October 31, 2022. An extension of the information collection request is currently being developed. The public will have an opportunity to review and submit comments regarding the extension of this PRA package through a public notice and comment period separate from this rulemaking. The preliminary, unaudited CY 2019 survey data were posted on the CMS website on September 8, 2020. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2023 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

2. Calculation of the Occupational Mix Adjustment for FY 2023

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28366), for FY 2023, we proposed to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2023 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, in order to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2

associated with this final rule (which is available via the internet on the CMS website), which contains the final FY 2023 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C. of the preamble of this final rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2023 wage index. For the proposed FY 2023 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,112 hospitals, and we used the occupational mix surveys of 3,010 hospitals for which we also had Worksheet S–3 wage data, which represented a ''response'' rate of 97 percent (3,010/3,112). For the proposed FY 2023 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2023 occupational mix adjusted national average hourly wage was $47.71.

We did not receive any comments on our proposed calculation of the occupational mix adjustment to the FY 2023 wage index. Thus, for the reasons discussed in this final rule and in the FY 2023 IPPS/LTCH PPS proposed rule, we are finalizing our proposal, without modification to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index and to apply the occupational mix adjustment to 100 percent of the FY 2023 wage index.

For the final FY 2023 wage index, we are using the Worksheet S3, Parts II and III wage data of 3,136 hospitals, and we are using the occupational mix surveys of 3,035 hospitals for which we also have Worksheet S–3 wage data, which is a ''response'' rate of 97 percent (3,035/3,136). For the final FY 2023 wage index, we are applying proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the final FY–2023 occupational mix adjusted national average hourly wage is the following:

FY 2023 Occupational Mix Adjusted National Average Hourly Wage	$47.73

F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the FY 2023 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this final rule, for FY 2023, we are applying the occupational mix adjustment to 100 percent of the FY 2023 wage index. We calculated the occupational mix adjustment using data from the 2019 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

The FY 2023 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$44.44
National LPN and Surgical Technician	$26.86
National Nurse Aide, Orderly, and Attendant	$18.54
National Medical Assistant	$19.53
National Nurse Category	$37.38

The national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2019 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) the following:

National Percentage of Hospital Employees in the Nurse Category	42%
National Percentage of Hospital Employees in the All Other Occupations Category	58%
Range of Percentage of Hospital Employees in the Nurse Category (CBSA Level)	Low of 20 Percent in one CBSA to a high of 66 percent in another CBSA

We compared the FY 2023 occupational mix adjusted wage indexes for each CBSA to the unadjusted wage indexes for each CBSA. Applying the occupational mix adjustment to the wage data resulted in the following:

Comparison of the FY 2023 Occupational Mix Adjusted Wage Indexes to the Unadjusted Wage Indexes by CBSA	
Number of Urban Areas Wage Index Increasing	231 (53.6%)
Number of Rural Areas Wage Index Increasing	27 (57.4%
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	123 (29.9%)
Number of Urban Areas Wage Index Increasing by 5 percent or More	4 (1.0%)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	12 (25.5%)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	0 (0%)
Number of Urban Areas Wage Index Decreasing	180 (45.9%)
Number of Rural Areas Wage Index Decreasing	20 (42.6%)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	77 (19.7%)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	3 (0.5%)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	8 (17.0%)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0%)
Largest Positive Impact for an Urban Area	7.20%
Largest Positive Impact for a Rural Area	4.19%
Largest Negative Impact for an Urban Area	-5.48%
Largest Negative Impact for a Rural Area	-2.55%
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	1 (0.5%)
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	0 (0%)

These results indicate that a smaller percentage of urban areas (53.6 percent) would benefit from the occupational mix adjustment than would rural areas (57.4 percent).

G. Application of the Rural Floor, Application of the Imputed Floor, Application of the State Frontier Floor, Continuation of the Low Wage Index Hospital Policy, and Budget Neutrality Adjustment

1. Rural Floor

Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the rural floor. Section 3141 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) also requires that a national budget neutrality adjustment be applied in implementing the rural floor.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we removed urban to rural reclassifications from the calculation of the rural floor to prevent inappropriate payment increases under the rural floor due to rural reclassifications, such that, beginning in FY 2020, the rural floor was calculated without including the wage data of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103). For FY 2023, we proposed to continue to calculate the rural floor without the wage data of hospitals that have reclassified as rural under § 412.103 (87 FR 28367–28368). Also, for the purposes of applying the provisions of section 1886(d)(8)(C)(iii) of the Act, effective beginning in FY 2020, we removed the data of hospitals reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act (84 FR 42333). In the IPPS/LTCH PPS proposed rule (87 FR 28367 and 28368), we proposed to continue to apply this policy for FY 2023.

We noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28368) that the FY 2020 rural floor policy and the related budget neutrality adjustment were the subject of pending litigation, including in *Citrus HMA, LLC, d/b/a Seven Rivers Regional Medical Center* v. *Becerra,* No. 1:20-cv-00707 (D.D.C.) (hereafter referred to as *Citrus*). On April 8, 2022, the district court in *Citrus* granted in part the plaintiff hospitals' motion for summary judgment and denied the Secretary's cross-motion for summary judgment. The court found that the Secretary did not have authority under section 4410(a) of the Balanced Budget Act of 1997 to establish a rural floor lower than the rural wage index for a state. We stated that while *Citrus* involves only FY 2020, the court's decision—which is subject to potential appeal—may have implications for FY 2023 payment rates. We stated that we were continuing to evaluate the court's decision, and although we proposed for the rural floor wage index policy (and the related budget neutrality adjustment) to continue for FY 2023, we stated we may decide to take a different approach in the final rule, depending on public comments or developments in the court proceedings.

Comments: Several commenters supported CMS's policy established beginning in FY 2020 to exclude the wage data of § 412.103 hospitals from the rural floor calculation. Some commenters specifically stated that this policy restores fairness in the wage index by preventing certain states from manipulating the wage index system to artificially inflate the wage indexes of hospitals in the state at the expense of all other states, due to the rural floor national budget neutrality adjustment required by section 3141 of Public Law 111–148.

Many commenters urged CMS to acquiesce to the district court's decision in *Citrus,* discontinue the policy of excluding the wage data of § 412.103 hospitals from the rural floor calculation, and revert to the policy that existed prior to FY 2020. The commenters stated their belief that the court's analysis was thorough and that continuing the rural floor policy would

only increase the agency's exposure to future lawsuits. Commenters asserted that the plain language of the statute does not provide for a free-floating rural floor that is not linked to the rural wage index. One of the commenters advocating for CMS to revert to the policy that applied prior to FY 2020 requested that if CMS does choose to continue its current rural floor policy in FY 2023, it should do so in a non-budget neutral manner.

Other commenters also suggested that along with including the wage data of § 412.103 hospitals in the rural floor calculation, CMS should include the wage data of § 412.103 hospitals for purposes of the calculation required by § 1886(d)(8)(C)(ii) of the Act. Two commenters specifically asserted that CMS should include the wage data of § 412.103 hospitals that also have an Medicare Geographic Classification Review Board (MGCRB) reclassification for purposes of the calculation required by § 1886(d)(8)(C)(ii) of the Act. Specifically, these commenters stated that when a geographically rural hospital has an active MGCRB reclassification to another area, CMS includes the wage data of the hospital in calculating the rural wage index of the state in which that hospital is located, if not doing so would reduce the wage index for that rural area, as described in § 1886(d)(8)(C)(ii) of the Act. However, the commenters stated that CMS does not treat the wage data of hospitals with a § 412.103 reclassification in addition to an MGCRB reclassification in the same manner as geographically rural hospitals with an MGCRB reclassification. A commenter stated that treating hospitals with dual § 412.103 and MGCRB reclassifications in the same manner as other rural hospitals for the calculation required by § 1886(d)(8)(C)(ii) would help address rural floor manipulation by mitigating the impact that one or two § 412.103 hospitals remaining rural for wage index purposes would have on the rural wage index and rural floor.

Response: We appreciate the commenters' input. In response to the comments supporting our proposal to continue our policy of excluding the wage data of § 412.103 hospitals from the rural floor calculation for FY 2023, we appreciate the concern regarding wage index manipulation, particularly arising from high wage hospitals in certain states reclassifying as rural under § 412.103 to inflate the rural wage index. However, as noted by a commenter, a national budget neutrality adjustment is required by section 3141 of Public Law 111–148. As stated in response to comments in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45175 through 45176) and in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56920), section 3141 requires that budget neutrality for the rural floor be applied ''through a uniform, national adjustment to the area wage index'' instead of within each State beginning in FY 2011 (75 FR 50160). Accordingly, we do not have the authority to calculate rural floor budget neutrality in a State-specific manner.

With regard to the comments concerning the district court's decision in *Citrus,* prior to FY 2020, it was our policy to have the rural wage index set the rural floor, resulting in identical wage index values for a state's rural area and rural floor. We changed that policy in the FY 2020 IPPS/LTCH PPS final rule to prevent inappropriate payment increases under the rural floor due to rural reclassifications under § 412.103 (84 FR 42332 through 42336). We explained that rather than raising the payment of some urban hospitals to the level of the average rural hospital in their State, as we believed was the intent of the rural floor policy, the rural floor calculation prior to FY 2020 enabled urban hospitals to have their payments raised to the relatively high level of one or more geographically urban hospitals reclassified as rural (84 FR 42334). This policy change beginning in FY 2020 to exclude § 412.103 hospitals from the rural floor calculation created a rural area wage index separate from the rural floor, with the rural floor for the state typically lower than the rural wage index.

We understand that our policy of setting a rural floor lower than the rural wage index for a state is inconsistent with the district court's decision in *Citrus.* Following our review of that decision and the comments we received on the proposed rule, we are finalizing a policy that calculates the rural floor as it was calculated before FY 2020. Specifically, for FY 2023 and subsequent years, we are finalizing a policy to include the wage data of hospitals that have reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) and have no additional form of reclassification (MGCRB or Lugar) in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

With regard to the application of the hold harmless policy that the commenters referenced at § 1886(d)(8)(C)(ii), the statute requires that a rural area be held harmless from the effects of hospitals reclassifying under Lugar or the MGCRB. Specifically, § 1886(d)(8)(C)(ii) states: ''If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as not being located in the rural area in a State, reduces the wage index for that rural area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection as if the hospitals so treated had not been excluded from calculation of the wage index for that rural area.''

The commenters suggest that CMS should include the wage data of § 412.103 hospitals that also have a MGCRB reclassification for purposes of the calculation required by § 1886(d)(8)(C)(ii), thereby treating hospitals with dual § 412.103 and MGCRB reclassifications no differently than geographically rural hospitals with MGCRB reclassifications for the hold-harmless comparison at § 1886(d)(8)(C)(ii). Specifically, this would involve calculating the rural area wage index including the data of all § 412.103 hospitals, and then comparing it to a wage index with the effect of MGCRB reclassifications and Lugar hospital statuses applied, in order to possibly hold the rural area harmless from the effect of MGCRB reclassifications and Lugar hospital statuses.

As we explained in response to a similar comment in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45181), CMS continues to treat § 412.103 hospitals as rural as required by the statute even if such hospitals have an additional MGCRB reclassification by affording the hospital the benefits of rural status, such as 340B program and RRC eligibility. However, in developing our policies for how hospitals with dual reclassifications would be treated in wage index calculations following our April 21, 2016 IFC (81 FR 23428 through 23438), CMS discussed the effect of simultaneous § 412.103 and MGCRB reclassifications. We stated that when there is both a § 412.103 reclassification and an MGCRB reclassification, the MGCRB reclassification would control for wage index calculation and payment purposes. We explained that ''In these circumstances, we believe it is appropriate to rely on the urban MGCRB reclassification to include the hospital's wage data in the calculation of the urban CBSA wage index. Further, we believe it is appropriate to rely on the

urban MGCRB reclassification to ensure that the hospital be paid based on its urban MGCRB wage index. While rural reclassification confers other rural benefits besides the wage index under section 1886(d) of the Act, a hospital that chooses to pursue reclassification under the MGCRB (while also maintaining a rural reclassification under § 412.103) would do so solely for wage index payment purposes.'' (81 FR 23434). We continue to believe that policy, developed through rulemaking, is appropriate, since MGCRB reclassifications are solely for wage index payment purposes. Furthermore, the approach the commenters suggest would constitute a significant change to our current policy for § 412.103 hospitals that also have a MGCRB reclassification, and would create numerous downstream effects across IPPS ratesetting that might not be favorable to hospitals, contrary to the commenters' intent. For example, some states would experience a decline in their rural wage index if we were to treat hospitals with dual § 412.103 and MGCRB reclassifications no differently than geographically rural hospitals with MGCRB reclassifications. In response to the commenters' assertion that such treatment would address rural floor manipulation, we note that the commenters' suggested treatment of hospitals with dual § 412.103 and MGCRB reclassifications would potentially allow for other forms of wage index manipulation. For example, high-wage hospitals could obtain § 412.103 status, reclassify back to their home area under the MGCRB, in order to have their § 412.103 rural reclassifications raise the rural wage index via the hold harmless provision at § 1886(d)(8)(C)(ii), without lowering the hospitals' own wage index. We did not propose the policy the commenters suggest, and it would constitute a significant change with numerous effects on the IPPS wage index. We do not think it would be appropriate to adopt such a policy without describing it in a proposed rule and obtaining public comments from all interested parties. Therefore, in this final rule we are not adopting the policy the commenters suggest.

Based on the district court's decision in *Citrus* and the comments we received, we are not finalizing our rural floor wage index policy as proposed, which would have excluded § 412.103 hospitals from the calculation of the rural floor and from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. Rather, we are finalizing a policy that calculates the rural floor as it was calculated before FY 2020. This decision follows our review of the decision in *Citrus* and the comments received, including comments urging us to revert to our pre-2020 policy. For FY 2023 and subsequent years, we are finalizing a policy to include the wage data of hospitals that have reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) and have no additional form of reclassification (MGCRB or Lugar) in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. We will apply the same policy as prior to the FY 2020 final rule for calculating the rural floor, in which the rural wage index sets the rural floor. Based on the FY 2023 wage index associated with this final rule (which is available via the internet on the CMS website) and based on the calculation of the rural floor including the wage data of hospitals that have reclassified as rural under § 412.103, we estimate that 275 hospitals would receive an increase in their FY 2023 wage index due to the application of the rural floor.

2. Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the imputed floor policy as a temporary 3-year regulatory measure to address concerns from hospitals in all urban States that have stated that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. We extended the imputed floor policy eight times since its initial implementation, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and expired on September 30, 2018. (We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FYs 2014 through 2019 (78 FR 50589 through 50590, 79 FR 49969 through 49971, 80 FR 49497 through 49498, 81 FR 56921 through 56922, 82 FR 38138 through 38142, and 83 FR 41376 through 41380, respectively) and to the regulations at 42 CFR 412.64(h)(4).) For FYs 2019, 2020, and 2021, hospitals in all-urban states received a wage index that was calculated without applying an imputed floor, and we no longer included the imputed floor as a factor in the national budget neutrality adjustment.

In computing the imputed floor for an all-urban State under the original methodology established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever was higher was multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State. We adopted a second, alternative methodology beginning in FY 2013 (77 FR 53368 through 53369) to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit another all-urban State, Rhode Island, which had only one CBSA. Under the alternative methodology, we first determined the average percentage difference between the post reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. The lowest post reclassified wage index assigned to a hospital in an all-urban State having a range of such values then was increased by this factor, the result of which established the State's alternative imputed floor. Under the updated OMB labor market area delineations adopted by CMS beginning in FY 2015, Delaware became an all-urban State, along with New Jersey and Rhode Island, and was subject to an imputed floor as well. In addition, we adopted a policy, as reflected at § 412.64(h)(4)(vi), that, for discharges on or after October 1, 2012, and before October 1, 2018, the minimum wage index value for a State is the higher of the value determined under the original methodology or the value determined under the alternative methodology. The regulations implementing the imputed floor wage index, both the original methodology and the alternative methodology, were set forth at § 412.64(h)(4).

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) enacted on March 11, 2021, amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in

an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Thus, effective beginning October 1, 2021 (FY 2022), section 1886(d)(3)(E)(iv) of the Act reinstates the imputed floor wage index policy for all-urban States, with no expiration date, using the methodology described in 42 CFR 412.64(h)(4)(vi) as in effect for FY 2018. As discussed previously, under § 412.64(h)(4)(vi), the minimum wage index value for hospitals in an all-urban State is the higher of the value determined using the original methodology (as set forth at § 412.64(h)(4)(i) through (v)) or the value determined using alternative methodology (as set forth at § 412.64(h)(4)(vi)(A) and (B)) for calculating an imputed floor. Therefore, as provided in § 412.64(h)(4)(vi), we apply the higher of the value determined under the original or alternative methodology for calculating a minimum wage index, or imputed floor, for all-urban States effective beginning with FY 2022. We note that the rural floor values used in the alternative methodology at § 412.64(h)(4)(vi)(A) and (B) would now include the wage data of hospitals reclassified under § 412.103 that have no additional form of reclassification (MGCRB or Lugar), according to the rural floor wage index policy finalized in this final rule in which we calculate the rural floor for FY 2023 including the wage data of such hospitals.

Unlike the imputed floor that was in effect from FYs 2005 through 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In other words, the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act, as amended, must be applied without taking into account the imputed floor adjustment under section 1886(d)(3)(E)(iv) of the Act. When the imputed floor was in effect from FY 2005 through FY 2018, to budget neutralize the increase in payments resulting from application of the imputed floor, we calculated the increase in payments resulting from the imputed floor together with the increase in payments resulting from the rural floor and applied an adjustment to reduce the wage index. By contrast, for FY 2022 and subsequent years, we apply the imputed floor after the application of the rural floor and apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor required under section 1886(d)(3)(E)(iv) of the Act.

The imputed floor under section 1886(d)(3)(E)(iv) of the Act applies to all-urban States, as defined in new subclause (IV). Section 1886(d)(3)(E)(iv)(IV) provides that, for purposes of the imputed floor wage index under clause (iv), the term all-urban State means a State in which there are no rural areas (as defined in section 1886(d)(2)(D) of the Act) or a State in which there are no hospitals classified as rural under section 1886 of the Act. Under this definition, given that it applies for purposes of the imputed floor wage index, we consider a hospital to be classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value. Therefore, under the definition at section 1886(d)(3)(E)(iv)(IV) of the Act, ''a State in which there are no hospitals classified as rural under this section'' includes a State that has a rural area but no hospitals that receive the rural area wage index under section 1886(d) of the Act. For purposes of this definition, hospitals redesignated as rural under section 1886(d)(8)(E) of the Act (412.103 rural reclassifications) are considered classified as rural if they receive the rural wage index; however, hospitals that are deemed urban under section 1886(d)(8)(B) of the Act (in Lugar counties), or are reclassified to an urban area under section 1886(d)(10) of the Act (MGCRB reclassifications) are not considered classified as rural because they do not receive the rural wage index. In contrast, we note that in the imputed floor policy in effect from FY 2005 through FY 2018, we did not consider a State to qualify for ''all urban status'' if there were one or more hospitals geographically located in the rural area of the State, even if all such hospitals subsequently reclassified to receive an urban area wage index. There is one State, Connecticut, that would be eligible for the imputed floor because there are currently no hospitals in Connecticut that are classified as rural under section 1886(d) for purposes of the wage index—in other words, there are no hospitals that receive the rural wage index. There is currently one rural county in Connecticut. All hospitals in this county are either deemed urban under section 1886(d)(8)(B) of the Act or receive an MGCRB reclassification under section 1886(d)(10) of the Act. While several Connecticut hospitals were approved for rural reclassification under section 1886(d)(8)(E) of the Act, at this point all have received a subsequent urban reclassification under section 1886(d)(10) of the Act.

Additionally, under section 1861(x) of the Act, the term State has the meaning given to it in section 210(h) of the Act. Because section 210(h) of the Act defines the word State to also include the District of Columbia and the Commonwealth of Puerto Rico, Washington, DC and Puerto Rico may also qualify as all-urban States for purposes of the imputed floor if the requirements of section 1886(d)(3)(E)(iv)(IV) of the Act are met. Based on data available for this final rule, the following States would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2023: New Jersey, Rhode Island, Delaware, Connecticut, and Washington, DC.

In the FY 2022 IPPS/LTCH PPS final rule, we revised the regulations at § 412.64(e)(1) and (4) and (h)(4) and (5) to implement the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2021. The imputed floor will be applied for FY 2023 in accordance with the policies adopted in the FY 2022 IPPS/LTCH PPS final rule. For more information regarding our implementation of the imputed floor required by section 1886(d)(3)(E)(iv) of the Act, we refer readers to the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178).

Comment: Several commenters supported the application of the imputed floor wage index policy, including the policy's definition of all-urban states as well as its non-budget neutral application as required by section 9831 of the American Rescue Plan Act of 2021. A commenter opposed the imputed floor policy, stating that it unfairly manipulates the wage index to benefit a handful of only-urban states and territories, but acknowledged that the imputed floor policy is derived from legislation enacted by Congress.

Response: We appreciate the commenters' support of our application of the statutory imputed floor policy. Responding to the commenter opposed to this policy, we underscore that, as the commenter pointed out, the imputed floor was established by section 9831 of the American Rescue Plan Act of 2021.

Accordingly, CMS does not have discretion to not apply the imputed floor.

After consideration of the public comments, we will apply the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2022 in accordance with our existing policies.

3. State Frontier Floor for FY 2023

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In the FY 2023 IPPS/LTCH PPS proposed rule, we did not propose any changes to the frontier floor policy for FY 2023. In the proposed rule we stated that 44 hospitals would receive the frontier floor value of 1.0000 for their FY 2023 proposed wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming.

We did not receive any public comments on the application of the State frontier floor for FY 2023. In this final rule, 44 hospitals will receive the frontier floor value of 1.0000 for their FY 2023 wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. We note that while Nevada meets the criteria of a frontier State, all hospitals within the State currently receive a wage index value greater than 1.0000. The areas affected by the rural and frontier floor policies for the final FY 2023 wage index are identified in Table 2 associated with this final rule, which is available via the internet on the CMS website.

4. Continuation of the Low Wage Index Hospital Policy; Budget Neutrality Adjustment

To help mitigate wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications under 42 CFR 412.103 in the rural floor, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized policies to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor. We also provided for a transition in FY 2020 for hospitals experiencing significant decreases in their wage index values as compared to their final FY 2019 wage index, and made these changes in a budget neutral manner.

We increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals (the low wage index hospital policy). We stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) our intention that this policy will be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. We noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28369) that the FY 2020 low wage index hospital policy and the related budget neutrality adjustment are the subject of pending litigation, including in *Bridgeport Hospital, et al.,* v. *Becerra,* No. 1:20–cv–01574 (D.D.C.) (hereafter referred to as *Bridgeport*). On March 2, 2022, the district court in *Bridgeport* granted in part the plaintiff hospitals' motion for summary judgment and denied the Secretary's cross-motion for summary judgment. The court found that the Secretary did not have authority under section 1886(d)(3)(E) or 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy and ordered additional briefing on the appropriate remedy. We stated that while *Bridgeport* involves only FY 2020, the court's decision—which is not final at this time and is also subject to potential appeal—may have implications for FY 2023 payment rates. We stated that we were continuing to evaluate the court's decision, and although we proposed the low wage index hospital policy (and the related budget neutrality adjustment, discussed in this section of this rule) to continue for FY 2023, we stated that we may decide to take a different approach in the final rule, depending on public comments or developments in the court proceedings. In order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, for FY 2023 and for subsequent fiscal years during which the low wage index hospital policy is in effect, we proposed to apply a budget neutrality adjustment in the same manner as we applied it in FYs 2020, 2021, and 2022, as a uniform budget neutrality factor applied to the standardized amount. We refer readers to section II.A.4.f. of the addendum to this final rule for further discussion of the budget neutrality adjustment for FY 2023. For purposes of the low wage index hospital policy, based on the data for this final rule, the table displays the 25th percentile wage index value across all hospitals for FY 2023. FY 2023 25th Percentile Wage Index Value 0.8427.

Comment: Many commenters supported the low wage index hospital policy. Commenters praised the low wage index hospital policy for already beginning to reduce wage index disparities and urged the agency to continue with the policy for FY 2023 as proposed. Commenters described dire consequences of the policy ending, with a commenter specifically stating that Medicare payments to hospitals in Puerto Rico could fall drastically. Numerous commenters representing hospitals in a state with relatively low wages indicated that they have used the increased payments resulting from the low wage index hospital policy as CMS intended, by raising compensation for their workers. However, these commenters stated that the national average hourly wage increased at an even higher rate due to COVID–19, indicating that additional time for the policy and continued efforts on behalf of low wage hospitals are required. A commenter requested that CMS consider the effects of COVID–19 as CMS decides how it will appropriately evaluate the effectiveness of its policy to raise low wage hospitals' wage indexes in the near future, and another commenter specifically requested that CMS extend the policy for at least four additional years due to COVID–19. A commenter stated that CMS should maintain the policy until CMS can verify that increased hospital compensation under the policy has led to increased wage indexes, consistent with original intent of the policy.

Response: We appreciate the many comments received in support of our low wage index hospital policy and the feedback regarding achievement of the intended policy goal. We appreciate the commenters' requests to consider the impacts of COVID–19, to extend this policy beyond four years due to COVID–19, and to extend the policy until the intended goals of the policy are reached. We appreciate commenters' suggestions on how we might evaluate the effectiveness of the policy and may consider those suggestions in future rulemaking.

Comment: Many commenters supported increasing the wage index values of low-wage hospitals, but urged CMS to do so in a non-budget-neutral

manner. Commenters stated that implementing the policy with a budget neutrality adjustment merely shifts funds from one group to another. Commenters urged CMS to consider wage index reforms that lift low wage hospitals' wage indexes without reducing the standardized operating rate for all hospitals, which commenters indicated already receive Medicare reimbursement at rates that are less than the actual cost of care. A commenter stated that for hospitals between the 22nd and 25th percentile, the reduction due to the budget neutrality adjustment is greater than the benefit received from the quartile adjustment. This commenter suggested holding hospitals under the 25th percentile harmless by slightly reducing the labor-related share for those hospitals that have a wage index greater than 1, or via a graduated reduction to the standardized rate based on wage index percentile. Other alternative methodologies and data suggested by commenters included: reducing the wage indexes of hospitals with wage index values above the 75th percentile through a budget neutrality adjustment; verifying local labor prices with wage data audits; working with Congress to create a new designated pool of funding; working with Congress to minimize wage index cliffs; shortening the lag in hospital wage data used to construct the wage index; and setting a national wage index floor of 1.000.

Response: We disagree with the commenters that the low wage index hospital policy should be implemented in a non-budget neutral manner. As we stated in response to similar comments in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331 and 42332) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45180), under section 1886(d)(3)(E) of the Act, the wage index adjustment is required to be implemented in a budget neutral manner. However, even if the wage index were not required to be budget neutral under section 1886(d)(3)(E) of the Act, we would consider it inappropriate to use the wage index to increase or decrease overall IPPS spending. As we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331), the wage index is not a policy tool but rather a technical adjustment designed to be a relative measure of the wages and wage-related costs of subsection (d) hospitals. As a result, as we explained in the FY 2020 IPPS/LTCH PPS final rule, if it were determined that section 1886(d)(3)(E) of the Act does not require the wage index to be budget neutral, we invoke our authority at section 1886(d)(5)(I) of the Act in support of such a budget neutrality adjustment.

With regard to the commenter's assertion about a possible reduction to overall payment if the amount of benefit received from the wage index boost is less than the reduction to the standardized amount, we believe we have applied both the quartile policy and the budget neutrality policy appropriately, as we explained in response to comments in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45180). The quartile adjustment is applied to the wage index, which resulted in an increase to the wage index for hospitals below the 25th percentile. The budget neutrality adjustment is applied to the standardized amount in order to ensure that the low wage index hospital policy is implemented in a budget neutral manner. Thus, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act and with how we implemented budget neutrality for the low wage index hospital policy in FY 2020, we believe it is appropriate to continue to apply a budget neutrality adjustment to the national standardized amount for all hospitals so that the low wage index hospital policy is implemented in a budget neutral manner for FY 2023.

We appreciate the commenters' range of suggested alternatives. Because we did not propose alternatives with regard to the low wage index hospital policy, we consider these comments to be outside the scope of the FY 2023 IPPS/LTCH PPS proposed rule. We are not addressing them in this final rule but may consider them in future rulemaking.

Comment: Several commenters opposed the low wage index hospital policy, stating that it is inappropriately redistributive, ineffective, and outside the agency's statutory authority under section 1886(d)(3)(E) of the Act. Specifically, a commenter stated that although the policy is intended to help rural hospitals, rural hospitals in certain states do not benefit from this policy. Furthermore, the commenter stated that the policy undermines the intent of the wage index by not recognizing real differences in labor costs.

Response: In response to comments opposing the low wage index hospital policy, we believe we addressed the stated concerns in our responses to comments when we first finalized the policy and the related budget neutrality adjustment in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42332). Concerning the policy's redistributive effect, we refer readers to our response to the comments above about budget neutrality. With regard to the policy's effectiveness, we believe the comments in support of the policy, specifically comments from relatively low-wage hospitals stating that the increased payments under the policy have allowed them to raise compensation for their workers, indicate that many low wage hospitals are benefiting from this policy. Furthermore, we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) our intention that this policy will be effective for at least 4 years, until the policy's effects could be reflected in the wage index data. In response to the comment stating that although the policy is intended to help rural hospitals, rural hospitals in certain states do not benefit from this policy, we refer readers to our response to a similar comment in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42328) regarding the policy's effect on rural hospitals.

In response to comments stating the policy exceeds CMS's statutory authority, we refer the commenters to our prior discussion of the authority for the policy in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42332).

In response to the commenter who asserted that the low wage index hospital policy does not recognize real differences in labor costs, we continue to believe, for the reasons stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42327–42328), that by preserving the rank order in wage index values, our policy continues to reflect meaningful distinctions between the employee compensation costs faced by hospitals in different geographic areas. Thus, under the low wage index hospital policy, we believe the wage index for low wage index hospitals appropriately reflects the relative hospital wage level in those areas compared to the national average hospital wage level.

Comment: Many commenters noted that the low wage index hospital policy is currently the subject of pending litigation in *Bridgeport.* A few commenters urged CMS not to finalize the policy for FY 2023, or to wait until a final court decision is reached. One such commenter suggested CMS should eliminate the budget neutrality adjustments for FYs 2020, 2021, and 2022 in light of *Bridgeport.* Many commenters urged CMS to appeal the district court's decision in *Bridgeport.* These commenters stated that the consequences of halting the policy would be dire, and that CMS has broad authority under section 1886(d)(3)(E) to make policy adjustments, such as the

imputed floor policy implemented in 2005 that was implemented by CMS as a policy measure to address concerns from hospitals in all-urban states. These commenters further stated that this step towards achieving health equity is justified, and that CMS implemented the low wage index hospital policy via notice-and-comment rulemaking.

Response: We appreciate the commenters' input. As we stated in the proposed rule, the FY 2020 low wage index hospital policy and the related budget neutrality adjustment are the subject of pending litigation, including in *Bridgeport.* As *Bridgeport* is pending litigation, we are unable to provide further information at this time. We disagree with the district court's conclusion that the Social Security Act does not authorize the Secretary to adopt the low wage index hospital policy, and we note that its decision remains subject to potential appeal. We also note that plaintiffs in *Bridgeport* only challenged the low wage index hospital and associated budget neutrality adjustment policies for FY 2020.

After consideration of the comments we received, and for the reasons stated above and in the proposed rule, we are finalizing as proposed to continue the low wage index hospital policy and the related budget neutrality adjustment for FY 2023.

H. FY 2023 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). In this FY 2023 IPPS/LTCH PPS final rule, as provided beginning with the FY 2021 IPPS/LTCH PPS final rule, we have included Table 4A which is titled ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' and Table 4B titled ''Counties redesignated under section 1886(d)(8)(B) of the Act (Lugar Counties).'' We refer readers to section VI. of the Addendum to this final rule for a discussion of the wage index tables for FY 2023.

I. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). We note that rural hospitals reclassifying under the MGCRB to another State's rural area are not eligible for the rural floor, because the rural floor may apply only to urban, not rural, hospitals.

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103 from the calculation of the rural floor. In section III.G.1 of this final rule, for FY 2023 and subsequent years, we are finalizing a policy that calculates the rural floor as it was calculated before FY 2020. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act and for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. We exclude hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930), in which we finalized the April 21, 2016 IFC, for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For a discussion on the effects of reclassifications under § 412.103 on the rural area wage index and the calculation of the rural floor for FY 2020 through FY 2022, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336). For a discussion of the effects of reclassifications under § 412.103 on the rural area wage index and the calculation of the rural floor for FY 2023 and subsequent years, we refer readers to section III.G.1 of this final rule.

On May 10, 2021, we published an IFC in the **Federal Register** (86 FR 24735 through 24739) that included provisions amending our regulations to allow hospitals with a rural redesignation to reclassify through the MGCRB using the rural reclassified area as the geographic area in which the

hospital is located. We revised our regulation so that the redesignated rural area, and not the hospital's geographic urban area, is considered the area a § 412.103 hospital is located in for purposes of meeting MGCRB reclassification criteria, including the average hourly wage comparisons required by § 412.230(a)(5)(i) and (d)(1)(iii)(C). Similarly, we revised the regulations to consider the redesignated rural area, and not the geographic urban area, as the area a § 412.103 hospital is located in for the prohibition at § 412.230(a)(5)(i) on reclassifying to an area with a pre-reclassified average hourly wage lower than the prereclassified average hourly wage for the area in which the hospital is located. Effective for reclassification applications due to the MGCRB for reclassification beginning in FY 2023, a § 412.103 hospital could apply for a reclassification under the MGCRB using the State's rural area as the area in which the hospital is located. We refer readers to the May 10, 2021 IFC (86 FR 24735 through 24739) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45187 through 45190), in which we finalized the May 10, 2021 IFC, for a full discussion of these policies.

2. MGCRB Reclassification and Redesignation Issues for FY 2023

a. FY 2023 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280. At the time this final rule was drafted, the MGCRB had completed its review of FY 2023 reclassification requests. Based on such reviews, there are 383 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2023. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2023, hospitals reclassified beginning in FY 2021 or FY 2022 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 311 hospitals approved for wage index reclassifications in FY 2021 that will continue for FY 2023, and 315 hospitals approved for wage index reclassifications in FY 2022 that will continue for FY 2023. Of all the hospitals approved for reclassification for FY 2021, FY 2022 and FY 2023, based upon the review at the time of the final rule, 1,009 hospitals are in a MGCRB reclassification status for FY 2023 (with 166 of these hospitals reclassified back to their geographic location).

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

We note that in the FY 2021 IPPS/LTCH final rule (85 FR 58771 through 58778), CMS finalized an assignment policy for hospitals reclassified to CBSAs from which one or more counties moved to a new or different urban CBSA under the revised OMB delineations based on OMB Bulletin 18–04. We provided a table in that rule (85 FR 58777 and 58778) which described the assigned CBSA for all the MGCRB cases subject to this policy. For such reclassifications that continue to be active or are reinstated for FY 2023, the CBSAs assigned in the FY 2021 IPPS/LTCH final rule continue to be in effect.

Applications for FY 2024 reclassifications are due to the MGCRB by September 1, 2022. We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained beginning in mid-July 2022, via the internet on the CMS website at *https://www.cms.gov/Regulations-andGuidance/Review-Boards/MGCRB/index.html*, or by calling the MGCRB at (410) 786–1174. This collection of information was previously approved under OMB Control Number 0938–0573 which expired on January 31, 2021. A reinstatement of this PRA package is currently being developed. The public will have an opportunity to review and submit comments regarding the reinstatement of this PRA package through a public notice and comment period separate from this rulemaking.

Comment: A commenter requested that in light of potential actions taken by CMS in response to the *Bridgeport* or *Citrus* decisions, CMS should allow an additional 45-day withdrawal/termination period after the publication of this final rule to allow hospitals to select the wage index that would apply for FY 2023. As an alternative, citing a FY 2005 policy exception, the commenter suggested that CMS can assign hospitals to the geographic area that is most advantageous to them.

Response: As previously discussed, in section III.G.4 of this final rule, CMS is finalizing as proposed to continue the low wage index hospital policy and the related budget neutrality adjustment for FY 2023 and is not implementing any changes at this time due to *Bridgeport.* As previously discussed, in section III.G.1. of the preamble of this final rule, we are modifying for FY 2023 and subsequent years the calculation of the rural floor and ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act, based on the *Citrus* decision. Presumably, the commenter is requesting that we provide an additional 45 days for hospitals with MGCRB reclassifications to submit MGCRB withdrawal or termination requests, or rescind such a request that was already approved. As previously discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49973) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58769—58770), we maintain that information provided in the proposed rule constitutes the best available data to assist hospitals in making reclassification decisions. In the proposed rule, we acknowledged the district court decisions in *Bridgeport* and *Citrus,* and we stated that we may decide to take a different approach to our policies in the final rule, depending on public comments or developments in the court proceedings. We believe hospitals had the ability to make informed decisions weighing potential outcomes based on the proposed rule.

In particular, we note that the state rural wage index published in Table 3 of the FY 2023 IPPS/LTCH PPS proposed rule would be the rural floor if we included 412.103 hospitals in the

calculation of the rural floor. Therefore, information with regard to what the rural floor would have been if we modified our policy was available in the proposed rule. Further, looking at the states and territories in Table 3 of the proposed rule, 40 states/territories in the proposed rule had a rural floor that equals the rural wage index (which includes Puerto Rico). Four states in the proposed rule are not eligible for the rural floor since they are all urban states and receive the imputed floor instead. Using data from Table 3 of the proposed rule, this leaves the 8 states listed in the table that follows with a difference between the state rural floor and state rural wage index. As demonstrated in the table that follows, hospitals should be able to make these MGCRB decisions based on the data in the proposed rule as usual as an overwhelming majority of the states/territories show no difference between the state rural wage index and state rural floor, and those that do show a difference show a minimal variance. Therefore, we do not believe the data justifies an additional 45 days for hospitals with MGCRB reclassifications to submit MGCRB withdrawal or termination requests or to rescind such a request that was already approved.

CBSA	Area Name	State Code	State Rural Wage Index	State Rural Floor	Difference Between State Rural Wage Index and State Rural Wage Index
02	ALASKA	02	1.1972	1.1880	-0.0092
03	ARIZONA	03	0.8560	0.8551	-0.0009
04	ARKANSAS	04	0.7508	0.7277	-0.0231
15	INDIANA	15	0.8589	0.8369	-0.0220
36	OHIO	36	0.8112	0.8083	-0.0029
39	PENNSYLVANIA	39	0.8354	0.8074	-0.0280
46	UTAH	46	0.9389	0.8666	-0.0723
50	WASHINGTON	50	1.0659	1.0180	-0.0479

In addition, as we discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58769—58770), section 1886(d)(8)(D) of the Act requires the Secretary to adjust the standardized amounts to ensure that the application of certain provisions of the statute, including a decision of the MGCRB or the Secretary under section 1886(d)(10), do not result in aggregate payments under section 1886 that are greater or less than those that would otherwise be made. If hospitals were to withdraw or terminate reclassification statuses after the publication of the final rule, as the commenter suggested CMS permit, any resulting changes in the wage index would not have been taken into account when calculating the IPPS standardized amounts in the final rule in accordance with the statutory budget neutrality requirement. Therefore, it is necessary that the values published in the final rule represent the final wage index values reflective of reclassification decisions.

With regard to the FY 2005 exception referenced by the commenter, CMS did provide an exception to the withdrawal and termination deadline due to the implementation of special reclassifications under section 508 of Pub. L. 108–173 and general concerns regarding the implementation of revised OMB labor market delineations based on the 2000 decennial census (69 FR 49060 and 49061). CMS inferred certain wage index selections for section 508 hospitals where the preferred option (depending on the finalization of proposed wage index policies) was clear and obvious, and hospitals were granted a 30 day window after the final rule to withdraw their reclassification request or to rescind their previous withdrawal or termination request. With the relatively few number of reclassified hospitals in FY 2005, it was plausible for CMS to impute or infer the optimal reclassification status in certain limited circumstances, and potentially allow for an additional window of opportunity for hospitals to review their options to withdraw or terminate MGCRB status. However, when factoring the large number of currently reclassified hospitals and the iterative and compounding impacts of various forms of wage index reclassification policy, various wage index floor policies, and other adjustment policies; it does not support the premise that additional opportunities to modify MGCRB reclassification status would be feasible or would result in more accurate or consistent results.

Comment: A commenter noted that the MGCRB issued determinations for FY 2023 on January 24, 2022. The commenter stated that this was earlier than in the past, when the MGCRB typically issued determinations mid-February, to meet the statutory requirement for decisions to be issued by the end of February. The commenter requested that CMS limit the MGCRB from issuing decisions prior to the first week of February to allow hospitals ample time to submit documentation of rural reclassification, SCH and RRC status to the Board or to submit a request to withdraw an application based on review of the January PUF. The commenter stated that without a more definitive timeline, hospitals face uncertainty if their documentation will be accepted by the MGCRB and could be adversely affected by an early decision being issued by the Board.

Response: We disagree with the commenter that hospitals are disadvantaged by earlier issuance of MGCRB decisions. First, we believe hospitals should submit applications complete with supporting documentation at the time MGCRB applications are due. Hospitals taking advantage of the MGCRB's practice of accepting supporting documentation to supplement applications until the date of the MGCRB's review are aware that the review is not held on the same date annually. Furthermore, rural reclassification may be obtained at any time, and hospitals seeking benefits of rural status for MGCRB reclassification

should plan accordingly. Finally, we note that hospitals dissatisfied with the MGCRB's decision may request the Administrator's review under § 412.278. With regard to hospitals requesting to withdraw a pending reclassification application following review of the January PUF, hospitals may withdraw a reclassification after the MGCRB has issued decisions, within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register**, per the regulations at § 412.273. Therefore, we do not believe hospitals are disadvantaged by the earlier timing of MGCRB decisions because they can submit supporting documentation timely, obtain a rural reclassification in advance, request the Administrator's review of an MGCRB decision, and withdraw an unwanted reclassification.

Comment: A commenter requested that CMS change the special rule for RRCs applying for reclassification at the MGCRB to afford hospitals the same reclassification opportunities as similar hospitals competing in the same labor market area. The commenter specifically suggested that CMS revise its regulations to state that if a hospital is located within five miles of another acute care hospital in the same CBSA with a lower average hourly wage, the hospital may reclassify to the same area as the lower wage hospital, if the applicable average hourly wage requirements are met, rather than to the area that is closest to the hospital.

Response: We appreciate the commenter's input. We did not propose any changes to the regulation referenced by the commenter, § 412.230(a)(3), the special rules for sole community hospitals and rural referral centers. We are not finalizing any changes to the special rule for RRCs applying for reclassification at the MGCRB in this final rule.

b. Clarification of Method for Submission Under § 412.273

The regulations at 42 CFR 412.273 set forth the procedures for withdrawing an MGCRB application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination (also referred to as a reinstatement). The timing of such requests is specified at § 412.273(c) for terminations and withdrawals and at paragraph (d)(2) for canceling a previous withdrawal or termination. However, the method of submission is not clearly specified in the regulations, other than the requirement that a request to cancel a previous withdrawal or termination (a reinstatement), or to withdraw an application or terminate an approved reclassification, be in writing according to § 412.273(d)(2) and (e). It has come to our attention that this may be a source of confusion for hospital representatives seeking to submit such requests. It is possible that hospital representatives would attempt to send such requests to the MGCRB via mail, email, or fax, rather than in the manner that the MGCRB can most efficiently track and process.

Beginning with applications from hospitals to reclassify for FY 2020, the MGCRB requires applications, supporting documents, and subsequent correspondence to be filed electronically through the MGCRB module of the Office of Hearings Case and Document Management System (''OH CDMS''). The MGCRB issues all of its notices and decisions via email and these documents are accessible electronically through OH CDMS. Registration instructions and the system user manual are available at *https://www.cms.gov/Regulations-and-Guidance/ReviewBoards/MGCRB/Electronic-Filing.html*.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42313), we revised the regulations at § 412.256(a)(1) to require applications for reclassification to be submitted to the MGCRB according to the method prescribed by the MGCRB. However, the regulations at § 412.273 for withdrawals, terminations, or cancelations of a previous withdrawal or termination (reinstatement) do not similarly specify a required manner of submission. Therefore, to eliminate potential confusion about how to submit withdrawal, termination, or cancelation (reinstatement) requests, we proposed to align the regulations at § 412.273 for withdrawal, termination, or cancelation (reinstatement) requests with the regulations at § 412.256 for new applications by specifying that withdrawal, termination, or cancelation (reinstatement) requests also must be submitted to the MGCRB according to the method prescribed by the MGCRB.

Specifically, we proposed to revise § 412.273(d)(2) for timing and process of cancellation requests and § 412.273(e) for withdrawal and termination requests. We proposed to revise § 412.273(d)(2) to state that cancellation requests must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year, as specified in § 412.256(a)(2). We also proposed to revise § 412.273(e) by adding that requests to withdraw an application or terminate an approved reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB. We stated that we believe these proposed revisions to the regulations would eliminate potential confusion; align our policy for withdrawals, terminations, and cancelations (reinstatements) with our policy for applications; and ensure requests are submitted to the MGCRB through the method for submission that they can most efficiently process.

Comment: A commenter supported the proposed changes to § 412.273. The commenter stated that these changes will eliminate potential confusion, align withdrawals, terminations, and cancellations with the MGCRB application process, and ensure submissions can be processed more efficiently by the MGCRB.

Response: We thank the commenter for supporting the proposed changes. After consideration of the public comment we received, we are finalizing as proposed without modification our changes to the regulations at § 412.273(d)(2) and (e).

3. Redesignations Under Section 1886(d)(8)(B) of the Act (Lugar Status Determinations)

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the outmigration adjustment. In addition, in that rule, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of publication of the proposed rule for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov*. In the FY 2018 IPPS/LTCH

PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to *wageindex@cms.hhs.gov*. To ensure proper accounting, we requested that hospitals include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the outmigration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located would no longer qualify for an out-migration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the outmigration adjustment would be denied, and the hospital would be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values would be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it would be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act.

We did not receive any requests to waive or reinstate an eligible hospital's deemed urban status under section 1886(d)(8)(B) of the Act. We did not receive any public comments on this policy for FY 2023.

J. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at that time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new outmigration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in prior IPPS/LTCH PPS final rules, most recently in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45184), we have applied the same policies, procedures, and computations since FY 2012. We proposed to use them again for FY 2023, as we believe they continue to be appropriate. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2023, the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-year) Microdata. For future fiscal years, we may consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate. For FY 2023, we did not propose any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).)

We did not receive any public comments on this proposed policy for FY 2023. Therefore, for the reasons set forth in this final rule and in the FY 2023 IPPS/LTCH PPS proposed rule, for FY 2023, we are finalizing our proposal, without modification, to continue using the same policies, procedures, and computations that were used for the FY 2012 outmigration adjustment and that were applicable for FYs 2016 through 2022.

Table 2 associated with this final rule (which is available via the internet on the CMS website) includes the out-migration adjustments for the FY 2023 wage index. In addition, Table 4A associated with this final rule, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' (also available via the internet on the CMS website) consists of the following: A list of counties that are eligible for the out-migration adjustment for FY 2023 identified by FIPS county code, the final FY 2023 out-migration adjustment, and the number of years the adjustment will be in effect.

K. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act Implemented at 42 CFR 412.103

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers

to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336) for a discussion of our policy to calculate the rural floor without the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103, and to section III.G.1 of this final rule for a discussion of our decision, for FY 2023 and subsequent years, to calculate the rural floor as it was calculated before FY 2020 by including the wage data of 412.103 hospitals.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41369 through 41374), we codified certain policies regarding multicampus hospitals in the regulations at 42 CFR 412.92, 412.96, 412.103, and 412.108. We stated that reclassifications from urban to rural under 42 CFR 412.103 apply to the entire hospital (that is, the main campus and its remote location(s)). We also stated that a main campus of a hospital cannot obtain an SCH, RRC, or MDH status, or rural reclassification under 42 CFR 412.103, independently or separately from its remote location(s), and vice versa. However, we are aware that some urban hospitals operate one or more remote location(s) in a State's rural area. In light of this scenario, we wish to clarify that rural reclassification under 42 CFR 412.103 applies to the main campus and any remote location located in an urban area. Under section 1886(d)(8)(E) of the Act, rural reclassification is available only to a hospital that is located in an urban area and satisfies the criteria specified in the statute. Thus, a remote location that is located in a rural area would not qualify for rural reclassification under section 1886(d)(8)(E) of the Act, as implemented under 42 CFR 412.103. We proposed to add 42 CFR 412.103(a)(8) to clarify that for a multicampus hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area, including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act.

We are also aware that CMS has not consistently reflected the 412.103 rural reclassification status in Table 2 of the annual IPPS/LTCH PPS rulemaking for certain remote locations of hospitals that are located in a different CBSA than the main campus. If a remote location of a hospital is located in a different CBSA than the main campus of the hospital, it is CMS's longstanding policy to assign that remote location a wage index based on its own geographic area in order to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act). Hospitals are required to identify and allocate wages and hours based on FTEs for remote locations located in different CBSA on Worksheet S–2, Part I, Lines 165 and 166 of form CMS–2552–10. In calculating wage index values, CMS identifies the allocated wage data for these remote locations in Table 2 with a ''B'' in the third position of the CCN.

As discussed previously, for a multicampus hospital, rural reclassification under 42 CFR 412.103 applies to the main campus and any remote location located in an urban area. The wage index implications of this policy are that, barring another form of wage index reclassification (for example, MGCRB reclassification), a main campus or remote location with approved 412.103 rural reclassification status would be assigned the rural wage index of its State. For FY 2023, we will list the 412.103 rural reclassification status for remote locations (a remote location is listed with a ''B'' in the third digit of the CCN) in Table 2 of the appendix to the final rule. We note that, as of the date this final rule is issued, only one ''B'' location (36B020) would be assigned its State's rural wage index in FY 2023 due to the § 412.103 rural reclassification status of the main provider (360020). This location appears to have ceased inpatient activities, so we do not expect a negative financial impact for FY 2023. However, hospitals with § 412.103 rural reclassification status and a remote location in a different CBSA should evaluate potential wage index outcomes for its remote location(s) when withdrawing or terminating MGCRB reclassification, or canceling 412.103 rural reclassification status. For example, if a hospital with 412.103 rural reclassification status withdraws a separate active MGCRB reclassification for a remote location, that remote location may be assigned the State's rural wage index value, effective for FY 2023.

Comment: A commenter supported our proposal to clarify that approved rural reclassification applies to a main campus and any remote locations in an urban area. The commenter stated that this policy allows for uniform treatment of all departments and campuses of the same hospital.

Response: We appreciate the commenter's support. Consistent with our clarification regarding multicampus hospitals, we are finalizing as proposed without modification our addition to the regulations at 42 CFR 412.103(a)(8) to clarify that for a multicampus hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area, including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act. Table 2 associated with this FY 2023 IPPS/LTCH PPS final rule will reflect the 412.103 rural reclassification status for remote locations of hospitals that are located in a different CBSA than the main campus.

L. Process for Requests for Wage Index Data Corrections

1. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files and the CY 2019 occupational mix data files for the proposed FY 2023 wage index were made available on May 24, 2021 through the internet on the CMS website at *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy2023-wage-index-home-page*.

On January 28, 2022, we posted a public use file (PUF) at *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy2023-wage-index-home-page* containing FY 2023 wage index data available as of January 28, 2022. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2018 through September 30, 2019; that is, FY 2019 wage data), a tab with the occupational mix data (which includes data from the CY 2019 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 28, 2022 wage data PUF, and a tab containing the CY 2019 occupational mix data of the hospitals deleted from the January 28, 2022 occupational mix PUF. In a memorandum dated January 20, 2022, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 28, 2022 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2023 Hospital Wage Index Development Time Table available at *https://www.cms.gov/files/document/fy2023-wi-time-table.pdf*.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums*.

In a memorandum dated May 11, 2021, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files and the CY 2019 occupational mix survey data files posted on May 24, 2021, and the process and timeframe for requesting revisions.

If a hospital wished to request a change to its data as shown in the May 24, 2021, preliminary wage data files and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 2, 2021. Hospitals were notified of these deadlines and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs. We note, CMS issued a waiver due to Hurricane Ida and modified the September 2, 2021, deadline specified in the FY 2023 Hospital Wage Index Development Time Table for certain hospitals. Specifically, CMS granted an extension until October 4, 2021, for hospitals in the States of Louisiana and Mississippi to request revisions to and provide documentation for their FY 2019 Worksheet S–3 wage data and CY 2019 occupational mix data as included in the May 24, 2021 preliminary Public Use Files (PUFs), respectively. According to the waiver, MACs must receive the revision requests and supporting documentation by October 4, 2021. If hospitals encountered difficulty meeting the extended deadline, hospitals were to communicate their concerns to CMS via their MAC for CMS to consider an additional extension if CMS determined it was warranted. Details regarding this waiver are available on the CMS website at *https://www.cms.gov/current-non-covid-emergencies*, Additional IPPS Hospital Blanket Waivers (*https://www.cms.gov/files/document/hurrican-ida-additional-ipps-hospital-blanket-waivers.pdf*). November 15, 2021, was the deadline for MACs to complete all desk reviews for hospital wage and occupational mix data and transmit revised Worksheet S–3 wage data and occupational mix data to CMS.

November 4, 2021, was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2022. CMS published the wage index PUFs that included hospitals' revised wage index data on January 28, 2022. Hospitals had until February 15, 2022, to submit requests to the MACs to correct errors in the January 28, 2022 PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the January 28, 2022, PUF. Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must be received by the MAC by the February deadline (that is, by February 15, 2022, for the FY 2023 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 18, 2022. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) was April 1, 2022. Data that were incorrect in the preliminary or January 28, 2022 wage index data PUFs, but for which no correction request was received by the February 15, 2022 deadline, are not considered for correction at this stage. In addition, April 1, 2022, was the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified after the January 28, 2022, PUF and at least 14 calendar days prior to April 1, 2022 (that is, March 18, 2022), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 1, 2022, for the FY 2023 wage index). We refer readers to the FY 2023 Hospital Wage Index Development Time Table for complete details.

Hospitals were given the opportunity to examine Table 2 associated with the proposed rule, which is listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-proposed-rule-home-page.* Table 2 associated with the proposed rule contained each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the proposed FY 2023 wage index which was constructed from FY 2019 data. We noted in the proposed rule that the proposed hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by early February 2022.

We posted the final wage index data PUFs on April 29, 2022 on the CMS website at *https://www.cms.gov/medicaremedicare-fee-service-payment acuteinpatientppswage-index-files/fy2023-wage-index-home-page*. The April 2022 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (the process for disputing revisions submitted to CMS by the MACs by March 18, 2022, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier).

After the release of the April 2022 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 18, 2022.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 28, 2022, wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2022 final wage index data PUFs, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital was given the opportunity to notify both its MAC and

CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital was required to send its request to CMS and to the MAC so that it was received no later than May 27, 2022. May 27, 2022, was also the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified on or after 13 calendar days prior to April 1, 2022 (that is, March 19, 2022), and at least 14 calendar days prior to May 27, 2022 (that is, May 13, 2022), that do not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital was notified on or after 13 calendar days prior to May 27, 2022 (that is, May 14, 2022), may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2023 Hospital Wage Index Development Time Table posted on the CMS website at *https://www.cms.gov/files/document/fy2023-wi-time-table.pdf*, the May appeals were required to be sent via mail and email to CMS and the MACs. We refer readers to the FY 2023 Hospital Wage Index Development Time Table for complete details.

Verified corrections to the wage index data received timely (that is, by May 27, 2022) by CMS and the MACs were incorporated into the final FY 2023 wage index, which will be effective October 1, 2022.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2023 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision is required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2022, they have an opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2023 wage index by August 2022, and the implementation of the FY 2023 wage index on October 1, 2022. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 27, 2022, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 27, 2022, for the FY 2023 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 27, 2022, deadline for the FY 2023 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 27, 2022 deadline for the FY 2023 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

2. Process for Data Corrections by CMS After the January 28 Public Use File (PUF)

The process set forth with the wage index time table discussed in section

III.L.1. of the preamble of this final rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 28 PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data that may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS would correct that data error and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 28 PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting review of such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency to instances where CMS makes data corrections after the January 28 PUF, and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2023 Hospital Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

M. Labor-Related Share for the FY 2023 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45208), we rebased and revised the hospital market basket. We established a 2018-based IPPS hospital market basket to replace the 2014-based IPPS hospital market basket, effective October 1, 2021. Using the 2018-based IPPS market basket, we finalized a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2021. In addition, in FY 2022, we implemented this revised and rebased labor-related share in a budget neutral manner (86 FR 45529–45530). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor related share if the costs are labor intensive and vary with the local labor market. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45204 through 45207), we included in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the 2018-based IPPS market basket: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-related Services. In the proposed rule, for FY 2023, we did not propose to make any further changes to the labor-related share. For FY 2023, we proposed to continue to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2022.

As discussed in section V.A. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor related share percentages that are applied to the national standardized amount. Accordingly, for FY 2023, we did not propose a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Comment: Some commenters stated that an analysis comparing hospitals' average hourly wages calculated from data reported on schedule S–3 of their FY 2019 to their 2020 cost reports shows that the average hourly wage rose 4.14 percent among hospitals with a wage index greater than 1.0. The commenters stated that this wage growth occurred at the same time that hospital utilization was decreasing due to the effects of the pandemic, resulting in a considerable increase in the portion of overall hospital costs represented by labor.

In addition to requesting that CMS update the labor share, the commenters requested that CMS modify its methodology to review only the labor costs of hospitals in areas with a wage index greater than 1.0 because hospitals in areas with a wage index lower than 1.0 receive a statutorily defined labor-related share of 62 percent. The commenters stated that changes of the labor share are budget-neutral but updating the share would ensure that a more appropriate amount of funds go to hospitals in areas with a wage index greater than 1.0, where the greatest increases in labor costs have been experienced. The commenters explained that the same comparison of 2019 and 2020 average hourly wages shows that hospitals with a wage index of 1.0 or less experienced an increase of only 2.38 percent during that same period.

For the reasons above, the commenters requested that CMS consider raising the labor-related share for hospitals with wage indexes greater than 1.0 for FY 2023.

A commenter stated that it strongly supports continuing to utilize a labor-related share of 67.6 percent for discharges. The commenter also stated that given the extreme increases in labor costs industry-wide due to the pandemic over the last three years, the commenter urged CMS to re-base again for FY 2023 to reflect a more accurate labor-related share.

A commenter stated that it experienced an exponential increase in the cost of labor as a result of the COVID–19 pandemic and labor shortages. The commenter requested that CMS evaluate the impact of rising labor costs on wage indices.

Response: We appreciate the commenters' concerns regarding how operating expenses for hospitals may have been impacted by the PHE. However, we disagree with the commenters' suggestion to update the labor related share for FY 2023. As published in the FY 2006 IPPS final rule (70 FR 47403), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket, including the labor-related share, of every four years. Therefore, in the FY 2022 IPPS/LTCH final rule, we finalized to update the labor related share to reflect the rebased and revised IPPS market basket, which is based on 2018 data. The labor-related share is equal to the national average proportion of operating costs that are attributable to the following cost categories in the 2018-based IPPS market basket: Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, and All Other: Labor-Related Services.

CMS did not propose to rebase and revise the IPPS market basket, including the labor-related share, in the FY 2023 IPPS/LTCH proposed rule. However, we did review the most recent Medicare cost report data available for IPPS hospitals submitted as of March 2022, which includes data for 2019–2020. The Medicare cost report data showed slight decreases in the compensation cost weight (reflecting wages and salaries, employee benefits, and direct patient care contract labor costs as a percent of operating costs) in 2019 and 2020 resulting in a compensation cost weight that is roughly 1 percentage point less than the 2018-based IPPS market basket cost weight. The compensation cost weight accounts for 53.0 percentage points of the 67.6 percentage point labor-related share based on the 2018-based IPPS market basket.

We plan to review the 2021 Medicare cost report data as soon as complete information is available and evaluate these data for future rulemaking. We thank the commenters for their comments and will consider the comments regarding the methodology for deriving the labor-related share for future rulemaking. After consideration of the public comments we received, for the reasons set forth above and in this final rule and in the FY 2022 IPPS/LTCH PPS final rule, we are finalizing our proposals, without modification, to continue to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2022 for all hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.0000.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2023 IPPS/LTCH PPS final rule and available via the internet on the CMS website, reflect the national labor-related share. Table 1C, in section VI. of the Addendum to this

FY 2023 IPPS/LTCH PPS final rule and available via the internet on the CMS website, reflects the national labor-related share for hospitals located in Puerto Rico. For FY 2023, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2023, we are applying the wage index to a labor-related share of 67.6 percent of the national standardized amount.

N. Permanent Cap on Wage Index Decreases

1. Permanent Cap Policy for the Wage Index

In the FY 2020 IPPS/LTCH PPS final rule, CMS implemented a transition policy for FY 2020 to place a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019 so that a hospital's final wage index for FY 2020 will not be less than 95 percent of its final wage index for FY 2019 (84 FR 42336 through 42337). We implemented this transition due to the combined effect of the policy changes for the FY 2020 wage index (including policies to address wage index disparities between high and low wage index hospitals), which we believed could lead to significant decreases in the wage index values for some hospitals. We stated that this transition would allow the effects of our policies to be phased in over 2 years with no estimated reduction in the wage index of more than 5 percent in FY 2020 (that is, no cap would be applied the second year). We also stated that we believed 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in the wage index for FY 2020. We applied a budget neutrality adjustment factor to the FY 2020 standardized amount for all hospitals to achieve budget neutrality for the transition policy (84 FR 42337 through 42338).

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755), to mitigate the effect of our adoption of the revised OMB delineations in OMB Bulletin 18–04, we implemented for FY 2021 the same 5 percent cap transition policy that we had implemented for FY 2020. Specifically, we placed a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a hospital's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020. We stated that for FY 2021, we did not believe it was necessary to implement the multifaceted transitions (including a 1-year blended wage index) we established in FY 2015 for the adoption of the new OMB delineations based on the new decennial census data. The 5 percent cap transition policy resulted in some hospitals receiving a transition adjustment that were not directly affected by the adoption of the revised OMB delineations (85 FR 58754). We applied a budget neutrality adjustment to the FY 2021 standardized amount to achieve budget neutrality for the transition policy (85 FR 58755).

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25397), given the unprecedented nature of the ongoing COVID–19 PHE, we solicited comments on whether it would be appropriate to continue to apply a transition to the FY 2022 wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04. We received several comments strongly recommending CMS extend a transition policy similar to that implemented in FY 2020 and FY 2021. Commenters also recommended CMS consider making a permanent 5 percent maximum reduction policy to protect hospitals from large year-to-year variations in wage index values as a means to reduce overall volatility. While we did not adopt the commenters' suggestion for a permanent 5 percent cap policy, we did finalize a transition policy for FY 2022 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45164). Specifically, for hospitals that received the transition in FY 2021, we continued a wage index transition for FY 2022 under which we apply a 5 percent cap on any decrease in the hospital's wage index compared to its wage index for FY 2021 to mitigate significant negative impacts of, and provide additional time for hospitals to adapt to, the CMS decision to adopt the revised OMB delineations. We applied a budget neutrality adjustment to the FY 2022 standardized amount so that the transition is implemented in a budget neutral manner (86 FR 45165).

For FY 2023 and subsequent years, we further considered the comments we received during the FY 2022 rulemaking recommending a permanent 5 percent cap policy to prevent large year-to-year variations in wage index values as a means to reduce overall volatility for hospitals. In the past, we have established temporary transition policies (as described above) when there have been significant changes to wage index policy, and we have limited the duration of each transition in order to phase in the effects of those policy changes. In taking this temporary approach in the past, we have sought to mitigate short-term instability and fluctuations that can negatively impact hospitals. We also recognize that, absent any specific change in wage index policy, significant year-to-year fluctuations in an area's wage index can occur due to external factors beyond a hospital's control, such as the COVID–19 PHE. For an individual hospital, these fluctuations can be difficult to predict. We recognize that predictability in Medicare payments is important to enable hospitals to budget and plan their operations.

In light of these considerations, in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed a permanent approach to smooth year-to-year decreases in hospitals' wage indexes (87 FR 28377 through 28380). We proposed a policy that we believe increases the predictability of IPPS payments for hospitals and mitigates instability and significant negative impacts to hospitals resulting from changes to the wage index. We stated that we also believe our proposed permanent policy would eliminate the need for temporary and potentially uncertain transition adjustments to the wage index in the future due to specific policy changes or circumstances outside hospitals' control (for example, in the event we adopt any future OMB revisions to the CBSA delineations). As a result of this proposed policy, an otherwise rare but relatively large year-to-year decrease in the wage index value for an individual hospital would be phased in, providing the hospital with additional time to plan appropriately and explore potential reclassification options, if applicable. For example, if a change in OMB delineations resulted in a hospital's wage index decreasing by more than 10 percent in any given year, this proposed policy could provide at least one additional year to phase in the decrease beyond a single ''transition'' year methodology, such as the transition policy finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49962).

Typical year-to-year variation in the wage index has historically been within 5 percent, and we stated in the proposed rule that we expect this will continue to be the case in future years. Because hospitals are usually experienced with this level of wage index fluctuation, we stated that we believe applying a 5-percent cap on all wage index decreases each year, regardless of the reason for the decrease, would effectively mitigate instability in IPPS payments due to any significant wage index decreases that may affect hospitals in a year. In

addition, we stated that we believe that the predictability resulting from a 5 percent cap on all wage index decreases would enable hospitals to more effectively budget and plan their operations. Because applying a 5-percent cap on all wage index decreases would represent a small overall impact on the labor market area wage index system, we stated that we believe it would ensure the wage index is a relative measure of the value of labor in prescribed labor market areas. In the proposed rule, we estimated that applying a 5-percent cap on all wage index decreases would have a very small effect on the budget neutrality factor associated with the cap applied to the standardized amount for FY 2023 (discussed in section III.N.2 of the preamble of the proposed rule). Because the wage index is a measure of the value of labor (wage and wage-related costs) in a prescribed labor market area relative to the national average, we stated that we anticipate that in the absence of policy changes most hospitals will not experience year-to-year wage index declines greater than 5 percent in any given year. Therefore, we stated that we anticipate that the impact to the budget neutrality factor associated with the cap in future years would continue to be minimal. We stated that we also believe that when the 5-percent cap would be applied under this proposal, in general it is likely that it would be applied similarly to all hospitals in the same labor market area, as the hospital average hourly wage data in the CBSA (and any relative decreases compared to the national average hourly wage) would be similar. While in certain circumstances this policy may result in some hospitals in a CBSA receiving a higher wage index than others in the same area, we stated that we believe the impact would be temporary.

For the reasons discussed in the proposed rule, we stated that we believe a 5-percent cap on wage index decreases would be appropriate for the IPPS. Therefore, for FY 2023 and subsequent years, we proposed to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, we proposed that a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. This also means that if a hospital's prior FY wage index is calculated with the application of the 5-percent cap, the following year's wage index would not be less than 95 percent of the hospital's capped wage index in the prior FY. For example, if a hospital's wage index for FY 2023 is calculated with the application of the 5-percent cap, then its wage index for FY 2024 would not be less than 95 percent of its capped wage index in FY 2023. We stated that we would reflect the proposed wage index cap policy at 42 CFR 412.64(h). Specifically, we proposed to add a new paragraph at 42 CFR 412.64(h)(7) to state that beginning with fiscal year 2023, if CMS determines that a hospital's wage index value for a fiscal year would decrease by more than 5 percent as compared to the hospital's wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

We stated that we have authority to implement the proposed wage index cap policy and the associated proposed budget neutrality adjustment (discussed in section III.N.2. of the preamble of the proposed rule) under section 1886(d)(3)(E) of the Act, which gives the Secretary broad authority to adjust for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, and requires those adjustments to be budget neutral. We also stated that in addition, we have authority to implement the proposed wage index cap policy and the associated proposed budget neutrality adjustment (discussed in section III.N.2. of the preamble of the proposed rule) as an adjustment under section 1886(d)(5)(I)(i) of the Act, which similarly gives the Secretary broad authority to provide by regulation for such other exceptions and adjustments to such payment amounts under subsection (d) as the Secretary deems appropriate.

We proposed to apply the wage index cap policy described above for a FY using the final wage index applicable to the hospital on the last day of the prior FY (except for newly opened hospitals, as discussed below). In general, the final wage index applicable to the hospital on the last day of the prior FY would be the wage index value listed for the hospital in Table 2 of the IPPS/LTCH PPS final rule for that prior FY (including any correction notices, if applicable). We stated that in rulemaking for a FY, we intend to relist the wage index values from Table 2 of the IPPS/LTCH PPS final rule for the prior FY, with updates as described below. Under the proposed wage index cap policy described above, we would use these values to determine a hospital's wage index for a FY by capping it at 95 percent of the final wage index applicable to the hospital on the last day of the prior FY (in general, the wage index value listed for the hospital in Table 2 of the IPPS/LTCH PPS final rule for the prior FY). We noted in the proposed rule that, consistent with our past application of the 5 percent cap transition policy (see the FY 2020 IPPS/LTCH PPS final rule (84 FR 42337)), the proposed wage index cap policy described above would apply to hospitals whose wage index is reduced by obtaining a urban to rural reclassification under 42 CFR 412.103. Specifically, a hospital that obtains a rural reclassification under 42 CFR 412.103 may be assigned its State's rural wage index.[212] While other forms of wage index reclassification are effective with the start of a Federal fiscal year, pursuant to 42 CFR 412.103(d)(1), the effective date of an approved rural reclassification is the filing date of the application. Therefore, the wage index values for hospitals that obtain rural reclassification under 42 CFR 412.103 may change in the middle of a Federal fiscal year and thus may not be reflected in Table 2 of the IPPS/LTCH PPS final rule for that year. For example, if a hospital was assigned its geographic wage index of 1.0001 in Table 2 of the FY 2022 IPPS/LTCH PPS final rule, but obtained a rural reclassification on December 1, 2021 and was assigned its state's rural wage index of 0.9600 for the remainder of FY 2022; the FY 2023 cap would be based on the 0.9600 value, not the 1.0001 value listed in Table 2 of the FY 2022 IPPS/LTCH PPS final rule. We stated that as in previous years, we would instruct hospitals that obtain a rural reclassification under 42 CFR 412.103 to contact their MAC to ensure that their assigned wage index does not result in a greater than 5 percent decrease from the hospital's prior year wage index value (see the FY 2020 IPPS/LTCH PPS final rule (84 FR 42337) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58754)).

In Table 2 associated with this final rule, which is available via the internet on the CMS website, we list the FY 2022 final wage index value for all hospitals in column C. For additional clarity, we have identified hospitals that have obtained rural reclassification after the FY 2022 lock-in date, as described in 42 CFR 412.103(b)(6), and that were assigned a different wage index than what was listed in Table 2 associated

[212] As discussed in the FY 2016 IFC (81 FR 23428 through 23438), hospitals with simultaneous reclassifications under 412.103 and either Lugar or MGCRB reclassification process are not assigned their State's rural wage index.

with the FY 2022 IPPS/LTCH PPS correction notice (available on the internet at *https://www.cms.gov/files/zip/fy-2022-ipps-frtables-2-3-4a-4b.zip*). In Table 2 associated with this final rule, the FY 2022 wage index column for these hospitals will not use the values listed in Table 2 associated with the FY 2022 IPPS/LTCH PPS correction notice (available on the internet at *https://www.cms.gov/files/zip/fy2022-ipps-fr-tables-2-3-4a-4b.zip*), but will instead be updated with the wage index value that is currently assigned to the hospitals. Under our proposal described above, we would apply the wage index cap using the actual final wage index value assigned to the hospital on the last day of the prior Federal fiscal year rather than the value listed in Table 2 of the prior FY final rule. In the proposed rule, we identified in Table 2 (posted on the FY 2023 proposed rule web page at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*) all hospitals that obtained rural reclassification under 42 CFR 412.103 after the FY 2022 lock-in date and that have no other form of wage index reclassification applicable to them at this time. This column in Table 2 has been revised for this final rule (posted on the FY 2023 final rule web page at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*) to add additional hospitals without another form of reclassification that obtain rural reclassification under 42 CFR 412.103 before the FY 2023 lock-in date as described in 42 CFR 412.103(b)(6).

We stated in the proposed rule that hospitals that obtain rural reclassification after the FY 2023 lock-in date will not be listed as being reclassified as rural in the FY 2023 IPPS/LTCH PPS final rule. We stated that if we finalize the proposed wage index cap policy described above, these hospitals should contact their MAC to ensure that the assigned rural wage index value is not less than 95 percent of their final wage index value for FY 2022 (that is, the wage index assigned to the hospital as of September 30, 2022).

For newly opened hospitals, we proposed to apply the proposed wage index cap policy for a FY using the wage index value the hospital was assigned for the prior FY. A new hospital would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it would not receive a cap for that first year because it would not have been assigned a wage index in the prior year. Also, it is possible a new hospital may not be listed in Table 2 for several years since the hospitals listed in Table 2 are based on historical data. We stated in the proposed rule that if we finalize the proposed wage index cap policy described above, a new hospital may contact their MAC to ensure that their assigned wage index value for the upcoming FY is not less than 95 percent of the value assigned to them for the prior Federal fiscal year. For example, if a hospital begins operations on July 1, 2022, and is assigned its area wage index of 0.9000 for the remainder of FY 2022, its FY 2023 wage index would be capped at 95 percent of that value, and could not be lower than 0.8550 (0.95×0.9000) regardless of whether it was listed in Table 2 in the FY 2022 IPPS/LTCH PPS final rule. A hospital that opens on December 1, 2022 would not be eligible for a capped wage index in FY 2023, as it was not assigned a wage index during FY 2022.

In the proposed rule, we noted that if we adopt these proposals as final policy, we would examine the effects of the policy on an ongoing basis in the future in order to assess whether it effectively and appropriately accomplishes the goal of increasing predictability and stability in IPPS payments.

We received comments on our proposals and summarize and respond to these comments in section III.N.2. below where we discuss the proposed budget neutrality adjustment associated with the proposed wage index cap policy. As we note below, we are finalizing our proposals regarding the wage index cap policy without modification.

2. Permanent Cap Budget Neutrality

We proposed to implement the proposed wage index cap policy (discussed above in section III.N.1 of the preamble of this final rule) in a budget neutral manner through a national adjustment to the standardized amount each fiscal year as we have implemented similar past transition policies involving a cap on wage index decreases (for example, see the FY 2021 IPPS/LTCH PPS final rule (85 FR 58755) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45164 through 45165)). We stated that we believe application of the proposed wage index cap policy should not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied the cap.

Specifically, we proposed to apply a budget neutrality adjustment to ensure that estimated aggregate payments under our proposed wage index cap policy for hospitals that would have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent would equal what estimated aggregate payments would have been without the proposed wage index cap policy. To determine the proposed associated budget neutrality factor, we stated that we would compare estimated aggregate IPPS payments with and without the proposed wage index cap policy. As discussed above in section III.N.1 of the preamble of this final rule, in the propose rule, we stated that we have authority to implement this budget neutrality adjustment under sections 1886(d)(3)(E) and (d)(5)(I)(i) of the Act.

Comment: Commenters were generally supportive of CMS's proposal to limit any decrease in a hospital's wage index value to be no greater than 5 percent as compared to the hospital's wage index value for the prior fiscal year. Commenters supported CMS's goal of increasing the stability and predictability of payments under the IPPS. However, several commenters contend that contrary to CMS's past statements, the statute neither authorizes nor requires budget neutrality to offset adjustments made under section 1886(d)(5)(I)(i). Some commenters suggested that CMS should apply the cap in a manner that would not reduce the wage indexes of other hospitals, contending this would lead to less volatility in wage index values. Several commenters request CMS review and seek alternatives to the proposed national budget neutrality adjustment.

Response: We appreciate commenters' support of the proposed permanent cap on wage index decreases. As discussed above in section III.N.1 of the preamble of this final rule, we have authority to implement the proposed budget neutrality adjustment associated with the proposed cap under sections 1886(d)(3)(E) and (d)(5)(I)(i) of the Act. Section 1886(d)(3)(E) gives the Secretary broad authority to adjust for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, and requires those adjustments to be applied in a budget neutral manner. However, even if the wage index were not required to be budget neutral under section 1886(d)(3)(E) of the Act, we would not consider it an appropriate alternative to use the wage index and the proposed permanent cap on wage index decreases to increase or decrease overall IPPS spending. The wage index is not a policy tool but rather a technical adjustment designed to be a relative measure of the wages and wage-related

costs of subsection (d) hospitals in the United States. Contrary to the commenters' assertion, we also have authority to implement the proposed budget neutrality adjustment associated with the proposed cap as an adjustment under section 1886(d)(5)(I)(i) of the Act, which similarly gives the Secretary broad authority to provide by regulation for such other exceptions and adjustments to such payment amounts under subsection (d) as the Secretary deems appropriate. Furthermore, our past transition policies involving a 5 percent cap on wage index decreases implemented in a budget neutral manner did not result in wage index volatility, and we expect the same for the overall budget neutrality adjustments associated with the permanent cap policy.

Comment: MedPAC supported the proposal to cap wage index decreases at 5 percent, but suggested also applying a cap to increases of more than 5 percent.

Response: We appreciate MedPAC's suggestion that the cap on wage index changes of more than 5 percent should also be applied to increases in the wage index. However, as we discussed in the proposed rule, one purpose of the proposed policy is to help mitigate the significant negative impacts of certain wage index changes. As we discussed in the proposed rule, we believe applying a 5-percent cap on all wage index decreases would support increased predictability about IPPS payments for hospitals in the upcoming fiscal year, enabling them to more effectively budget and plan their operations. That is, we proposed to cap decreases because we believe that a hospital would be able to more effectively budget and plan when there is predictability about its expected minimum level of IPPS payments in the upcoming fiscal year. We did not propose to limit wage index increases because we do not believe such a policy is needed to enable hospitals to more effectively budget and plan their operations. Therefore, we believe it is appropriate for hospitals that experience an increase in their wage index value to receive that wage index value.

Comment: A commenter suggested that if CMS discontinues the low wage index hospital policy, hospitals that benefitted in the prior year from that policy should not be subject to a 5 percent cap on any decreases.

Response: We appreciate the commenter's suggestion. As discussed in section III. G. 4 of this final rule, CMS is continuing the low wage index hospital policy for FY 2023.

Comment: A commenter did not support CMS's proposed policy approach to the wage index cap policy with regard to newly opened hospitals. While the commenter stated they understand the rationale for CMS's policy approach, they expressed concerns that it will create inequity in Medicare payments for hospitals within the same market. The commenter encouraged CMS to apply the same area wage index value for new and existing hospitals under this policy.

Response: We understand the commenter's concern, but we do not believe the scenario they are alluding to (that is, a labor market where existing hospitals are receiving the cap, and new hospitals are not) would neither be common nor require additional consideration. We believe that on an ongoing basis, relatively few hospitals would receive the cap, and even fewer would receive the cap in consecutive years. As of this final rule, there will be 126 hospitals receiving the cap in FY 2023, and only 12 that will receive a cap increase of greater than 5 percent. Therefore, any potential difference in the wage index value hospitals in the same labor market area receive would likely be minimal and temporary. We proposed to examine the effects of this policy on an ongoing basis to assess whether it effectively and appropriately accomplishes the goal of increasing predictability and stability in IPPS payments, and may reevaluate this issue in the future. However, at this time, we do not believe that creating a policy modification for hospitals that were not assigned a wage index in the prior year is necessary.

After consideration of the public comments we received, for the reasons discussed in this final rule and in the proposed rule, we are finalizing as proposed, without modification, our wage index cap policy and the associated budget neutrality adjustment. We will apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. A hospital's wage index for FY 2023 will not be less than 95 percent of its final wage index for FY 2022, and for subsequent years, a hospital's wage index will not be less than 95 percent of its final wage index for the prior FY. For example, a hospital that received a wage index of 1.0000 on September 30, 2022 could not receive a wage index of less than 0.9500 for FY 2023. If a hospital's prior FY wage index is calculated with the application of the 5-percent cap, the following year's wage index will not be less than 95 percent of the hospital's capped wage index in the prior FY. Except for newly opened hospitals, we will apply the cap for a FY using the final wage index applicable to the hospital on the last day of the prior FY. A newly opened hospital would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it would not receive a cap for that first year because it would not have been assigned a wage index in the prior year.

We are adding a new paragraph at 42 CFR 412.64(h)(7) to state that beginning with fiscal year 2023, if CMS determines that a hospital's wage index value for a fiscal year would decrease by more than 5 percent as compared to the hospital's wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

We will apply the cap in a budget neutral manner through a national adjustment to the standardized amount each fiscal year. Specifically, we will apply a budget neutrality adjustment to ensure that estimated aggregate payments under our wage index cap policy for hospitals that would have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent would equal what estimated aggregate payments would have been without the wage index cap policy. We note that the budget neutrality adjustment has been updated based on the final rule data. We refer readers to the Addendum of this final rule for further information regarding the budget neutrality calculations.

IV. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2023 (§ 412.106)

A. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's

geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

DSH Eligibility	Qualifying Criteria
Statutory Formula	A hospital that has a disproportionate patient percentage equal to or exceeding 15 percent, may qualify for the Medicare DSH adjustment. We refer readers to 42 CFR 412.106 for the specific eligibility criteria and payment formulas.
"Pickle Method"	A hospital that is located in an urban area and has 100 or more beds may qualify to receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this final rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

Since FY 2014, section 1886(r) of the Act has required that hospitals that are eligible for DSH payments under section 1886(d)(5)(F) of the Act receive 2 separately calculated payments:

Medicare DSH Payment	An empirically justified DSH payment equal to 25% of the amount determined under the statutory formula in section 1886(d)(5)(F) of the Act for Medicare DSH payments
Medicare DSH Uncompensated Care Payment	An uncompensated care payment determined as the product of the 3 factors, as discussed in this section.

Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus a statutory adjustment of 0.2 percentage point for FYs 2018 and 2019.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.'' In brief, the uncompensated care payment for an individual hospital is determined as the product of the following 3 factors:

Factor 1	75% of the total amount of DSH payments that would otherwise made under section 1886(d)(5)(F) of the Act.
Factor 2	1 minus the percent change in the percent of individuals who are uninsured (minus 0.2 percentage point for FYs 2018 and 2019). For FY 2020 and after, there is no additional reduction.
Factor 3	The hospital's uncompensated care amount relative to the uncompensated care amount for all DSH hospitals expressed as a percentage.

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which was established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

B. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As explained earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section

1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). For the proposed rule, we estimated DSH status for all hospitals using the most recent available SSI ratios and information from the most recent available Provider Specific File. We noted FY 2019 SSI ratios available on the CMS website were the most recent available SSI ratios at the time of developing the proposed rule. If more recent data on DSH eligibility become available before the final rule, we stated that we would use such data in the final rule. For this FY 2023 IPPS/LTCH PPS final rule, the FY 2020 SSI ratios were available at the time of developing this final rule. Our final determination of a hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for FY 2023.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemaking for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. In the FY 2023 IPPS/LTCH PPS proposed rule, we discussed our specific policies regarding eligibility to receive empirically justified Medicare DSH payments and uncompensated care payments for FY 2023 with respect to the following hospitals.

Eligible hospitals include the following:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act (78 FR 50623 and 79 FR 50006).
- *SCHs that are paid under the IPPS Federal rate* receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).
- *Medicare-dependent, small rural hospitals (MDHs)* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for interim empirically justified Medicare DSH and interim uncompensated care payments as we do for all other IPPS hospitals.

Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for discharges on or after October 1, 2017, through September 30, 2022. We note that there has not been legislation at the time of development of this final rule that would extend the MDH program beyond September 30, 2022. However, if the MDH program were to be extended beyond its current expiration date, similar to how it was extended under the Bipartisan Budget Act of 2018, we would continue to make a determination concerning an MDH's eligibility for interim uncompensated care payments based on the hospital's estimated DSH status for the applicable fiscal year.

- *IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model starting October 1, 2018,* will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. The BPCI Advanced Model's final performance year will end on December 31, 2023. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at *https://innovation.cms.gov/initiatives/bpci-advanced/*.
- *IPPS hospitals that participate in the Comprehensive Care for Joint Replacement Model* (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. We refer the reader to the interim final rule with request for comments that appeared in the November 6, 2020, **Federal Register** for a discussion of the Model (85 FR 71167 through 71173). In that interim final rule, we extended the Model's Performance Year 5 to September 30, 2021. In a subsequent final rule that appeared in the May 3, 2021 **Federal Register** (86 FR 23496), we further extended the Model for an additional three performance years. The Model's Performance Year 8 will end on December 31, 2024.

Ineligible hospitals include the following:

- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41402 through 41403), CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model, which began on January 1, 2019. Under the Maryland TCOC Model, Maryland hospitals will not be paid under the IPPS in FY 2023, and will be ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.
- *Sole community hospitals* (*SCHs*) *that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments.
- *Hospitals participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 114–255). The period of performance for this 5-

year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. The period of performance for this 5-year extension period ended December 31, 2021. The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) amended section 410A of Public Law 108–173 to extend the Rural Community Hospital Demonstration Program for an additional 5-year period. The period of participation for the last hospital in the demonstration under this most recent legislative authorization would extend until June 30, 2028, as outlined in section V.K. of the preamble of this final rule. Under the payment methodology that applies during the third 5-year extension period for the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are also excluded from receiving interim and final uncompensated care payments. At the time of development of this final rule, we believe 26 hospitals may participate in the demonstration program at the start of FY 2023.

We received no comments on our policy of using the best available data regarding a hospital's estimated DSH status for purposes of determining eligibility for interim uncompensated care payments for FY 2023. Our final determination of a hospital's eligibility for uncompensated care payments for FY 2023 will continue to be based on the hospital's actual DSH status at cost report settlement for the payment year.

C. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising Medicare Administrative Contractors (MACs) to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html*.

We received public comments that were outside the scope of this proposed rule. Many of these comments related to structural changes to the DSH program. For example, a commenter recommended creating new Conditions of Participation and Conditions of Coverage related to the DSH program. Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule.

D. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. In this section of this final rule, we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2022, and our final policies for FY 2023.

1. Calculation of Factor 1 for FY 2023

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between: (1) the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated).

Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount. Therefore, Factor 1 is the difference between our estimates of: (1) the amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28383 through 28385), in order to determine Factor 1 in the uncompensated care payment formula for FY 2023, we proposed to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified

Medicare DSH payments to hospitals under section 1886(r)(1) of the Act. Consistent with the policy that has applied in previous years, we proposed that these estimates would not be revised or updated subsequent to the publication of our final projections in this FY 2023 IPPS/LTCH PPS final rule.

Therefore, in order to determine the two elements of proposed Factor 1 for FY 2023 (Medicare DSH payments prior to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments after application of section 1886(r)(1) of the Act), for this final rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary (OACT) using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File. The determination of the amount of DSH payments is partially based on OACT's Part A benefits projection model. One of the results of this model is inpatient hospital spending. Projections of DSH payments require projections for expected increases in utilization and case-mix. The assumptions that were used in making these projections and the resulting estimates of DSH payments for FY 2020 through FY 2023 were discussed in the proposed rule in the table titled ''Factors Applied for FY 2020 through FY 2023 to Estimate Medicare DSH Expenditures Using FY 2019 Baseline'' (87 FR 28384).

For purposes of calculating the proposed Factor 1 and modeling the impact of the FY 2023 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's January 2022 Medicare DSH estimates, which were based on data from the September 2021 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2022 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2022 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the January 2022 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals, which are not eligible to receive DSH payments, were also excluded from the Office of the Actuary's January 2022 Medicare DSH estimates. The 26 hospitals that are anticipated to participate in the Rural Community Hospital Demonstration Program in FY 2023 were also excluded from these estimates, because under the payment methodology that applies during the third 5-year extension period, these hospitals are not eligible to receive empirically justified Medicare DSH payments or uncompensated care payments.

For the proposed rule, using the data sources as previously discussed, the Office of the Actuary's January 2022 estimate of Medicare DSH payments for FY 2023 without regard to the application of section 1886(r)(1) of the Act, was approximately $13.266 billion. Therefore, also based on the January 2022 estimate, the estimate of empirically justified Medicare DSH payments for FY 2023, with the application of section 1886(r)(1) of the Act, was approximately $3.316 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2023). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two OACT estimates. Therefore, in the proposed rule, we proposed that Factor 1 for FY 2023 would be $9,949,258,556.56, which was equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2023 ($13,266 million minus $3,316 million). In the FY 2023 IPPS/LTCH PPS proposed rule, we noted that consistent with our approach in previous rulemakings, OACT intended to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for this FY 2023 IPPS/LTCH PPS final rule.

As we noted in the FY 2023 IPPS/LTCH PPS proposed rule, the Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rules are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at *https://www.whitehouse.gov/omb/budget*. Consistent with historical practice, we indicated that we expected that the Midsession Review would have updated economic assumptions and actuarial analysis, which would be used for the development of Factor 1 estimates in the final rule.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2021 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds* under ''Downloads.'' We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections (available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/MedicaidReport*).

Comment: As in previous years, a concern and/or request expressed by some commenters was the need for greater transparency in the methodology used by CMS and OACT to calculate Factor 1. Several commenters specifically requested that a detailed description of the methodology and the data behind the assumptions be made public. Commenters requested that this information be provided in advance of the publication of the final rule and in the IPPS proposed rule each year going forward, so that the data is available to replicate CMS' DSH calculation and comment sufficiently in future years.

In particular, commenters requested further explanation regarding the estimate of the ''Other'' factor used to estimate Medicare DSH payments. Commenters noted that the rule did not discuss why the ''Other'' factor varies so much over successive rule making cycles.

Additionally, a commenter asserted that the lack of opportunity afforded to hospitals to review the data used in rulemaking is in violation of the Administrative Procedure Act and

expressed concerns about the lack of transparency in how Factor 1 is calculated, arguing that hospitals cannot meaningfully comment on the methodology given the lack of details. In particular, this commenter asserted that the proposed rule neither provided sufficient details nor an explanation of the treatment of Medicaid expansions in the calculation for Factor 1.

Response: We thank the commenters for their input. We disagree with commenters' assertion regarding the lack of transparency with respect to the methodology and assumptions used in the calculation of Factor 1. As explained in the FY 2023 IPPS/LTCH PPS proposed rule and in this section of this final rule, we have been and continue to be transparent about the methodology and data used to estimate Factor 1. Regarding the commenters who reference the Administrative Procedure Act, we note that, under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2023 IPPS/LTCH PPS proposed rule did include a detailed discussion of our proposed Factor 1 methodology and the data sources that would be used in making our final estimate. Accordingly, we believe interested parties were able to meaningfully comment on our proposed estimate of Factor 1.

To provide context, we note that Factor 1 is not estimated in isolation from other projections made by OACT. The Factor 1 estimates for the proposed rules are generally consistent with the economic assumptions and actuarial analyses used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/budget.* For additional information on the specific economic assumptions used in the Midsession Review of the President's FY 2023 Budget, we refer readers to the ''Midsession Review of the President's FY 2023 Budget'' also available on the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/budget.* We recognize that our reliance on the economic assumptions and actuarial analyses used to develop the President's Budget and the Midsession Review of the President's Budget in estimating Factor 1 has an impact on hospitals, health systems, and other impacted parties who wish to replicate the Factor 1 calculation, such as modeling the relevant Medicare Part A portion of the budget. Yet, we believe commenters are able to meaningfully comment on our proposed estimate of Factor 1 without replicating the budget.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2022 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html* under ''Downloads.'' We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid which is available on the CMS website at: *https://www.cms.gov/files/document/2018-report.pdf* for a discussion of general issues regarding Medicaid projections. Additionally, as described in more detail later in this section, in the FY 2023 IPPS/LTCH PPS proposed rule, we included information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's estimate of Factor 1. In summary, we indicated the historical HCRIS data update OACT used to identify Medicare DSH payments. We explained that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provided the components of all update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also included a description of the ''Other'' and ''Discharges'' assumptions, as well as additional information regarding how we address Medicaid and CHIP expansion.

For further information on our assumptions regarding Medicaid expansion in the Factor 1 calculation, we provide a discussion of more recent estimates and assumptions regarding the Medicaid expansion as part of the discussion of the final Factor 1 for FY 2023. This discussion also incorporates the estimated impact of the COVID–19 public health emergency (PHE.)

Comment: Many commenters questioned the proposed rule's estimate of the ''Discharge'' component of the Factor 1 calculation. Commenters requested clarity on the Factor 1 calculations, which assume small increases in discharge volume for FY 2022 and FY 2023.

Commenters noted that they are seeing trends that indicate that FY 2022 and FY 2023 discharge volumes, even though lower than pre-PHE levels, will continue to increase substantially. Some commenters urged CMS to reflect the same assumptions that the agency described in the ''April 2022 Announcement of CY 2023 Medicare Advantage Capitation Rates and Part C and Part D Payment Policies,'' where the agency made assumptions that Medicare ''utilization will begin to rebound.'' Other commenters referenced a Kaufman Hall study, and stated that adjusted national patient volume has increased by 18 percent from February 2022 to March 2022. A commenter referred to their own analysis of Medicare-Fee-For-service (FFS) claims data from the Chronic Condition Warehouse (CCW), which indicated that non-COVID–19 inpatient hospital discharge volume increased 22 percent from February to March 2022. Other commenters provided anecdotal data from their own hospitals and service regions that show continued sustained volumes in 2022. These commenters urged CMS to carefully monitor changes in discharge volume when estimating Factor 1.

Commenters also urged CMS to use a later update to the claims data to capture more of the increases in utilization that are anticipated for FY 2022. Commenters noted that the ''Discharge'' factor used by the OACT in estimating DSH expenditures was based on the December 2021 update of the MedPAR file, which includes data impacted by the PHE from FY 2021 and the first three months of FY 2022. Some commenters requested that CMS adjust the data used in the Factor 1 calculation for COVID–19 PHE impacts while others suggested that CMS exclude data from the latter parts of CY 2021 and early CY

2022. Other commenters urged CMS to consider excluding FY 2020 and FY 2021 discharges from the FY 2023 Factor 1 calculation, as data from those years include atypical trends in Medicare discharges due to the COVID–19 PHE.

Commenters pointed out that omitting FY 2020 and FY 2021 data would be consistent with CMS' exclusion of FY 2020 data in setting FY 2022 payment rates and the agency's proposal to exclude FY 2020 data from the per-discharge calculation in the FY 2023 IPPS/LTCH PPS proposed rule. Further, some commenters noted that the completion factor CMS used to estimate discharge volumes for FY 2021 and FY 2022 may not fully account for discharges due to billing delays as a result of PHE-related staffing shortages.

Finally, two commenters requested that for the FY 2024 IPPS/LTCH PPS proposed rule, CMS consider using the latest available data for the factors used to estimate Medicare DSH expenditures for purposes of calculating Factor 1 to avoid as much change in the estimate of Factor 1 between the proposed and final rules for FY 2024.

Some commenters also raised concerns about the ''Case Mix'' update factor used in the proposed FY 2023 Factor 1 calculation. Commenters stated that the proposed ''Case Mix'' update factor underestimates the complexity of patients returning to seek care following postponement or deferral of care during the COVID–19 PHE. Commenters also stated that CMS was using assumptions that are inconsistent with those that were used to develop the 2023 Medicare Advantage capitation payments, where the agency indicated an expectation that utilization will rebound in 2022 and finalized a risk score increase of 3.5 percentage points with the underlying assumption that patients put off seeking medical care throughout the PHE. Other commenters cited data from Kaufman Hall that indicate that hospitals are beginning to see more complex patients as shown by a nearly 5 percent increase in the average hospital length of stay in 2022 as compared to 2021.

Response: We thank the commenters for their input on the impact of the COVID–19 PHE on the factors used to estimate DSH payments for FY 2023. In updating our estimate of Factor 1 for this final rule, we considered, as appropriate, the same set of factors that we used in the proposed rule, which reflects the impact of the COVID–19 PHE. We then updated estimates for the ''Discharges'' and ''Case Mix'' factors to incorporate the latest available data. We provide further details on the updated Factor 1 estimate and data sources as part of the discussion of the final Factor 1 estimate for FY 2023 in this section of the rule.

Regarding the comments requesting that we exclude and/or mitigate the impacts of the COVID–19 PHE when estimating Factor 1 for FY 2023, we note that the statute specifies that Factor 1 is based on the amount of disproportionate share payments that would otherwise be made to subsection (d) hospitals for the fiscal year. As discussed further in this section, OACT's estimates of Medicare DSH payments used in the development of Factor 1, reflect the estimated impact of the COVID–19 PHE on DSH payments during FY 2023.

We also note that, with regard to the commenters' questions and concerns about the use of completion factors to adjust preliminary data, OACT assumed a discharge completion factor of 0 percent for FY 2020 and 0 percent for FY 2021. We believe these assumptions are consistent with historical patterns of completion factors that have been determined for discharges and appropriately account for incomplete claims data. We do not believe that excluding data from certain periods is necessary to estimate DSH payments during FY 2023 for purposes of the Factor 1 calculation, as required by the statute.

Regarding the comments requesting that CMS apply the same assumptions the agency made when setting Medicare Advantage payment rates, we note that Medicare Advantage and Medicare FFS are distinct programs. Accordingly, the estimates for the ''Discharges'' and ''Case Mix'' factors used to estimate Medicare DSH expenditures incorporate OACT's analyses of ''Discharges'' and ''Case Mix'' using only claims from the Medicare FFS program rather than claims from the Medicare Advantage program.

In response to commenters' request that CMS use the latest available estimates of historical data to avoid as much change in the DSH Factor 1 estimate between the proposed and final rules for FY 2024, we believe that the use of the most recent available data at the time of the proposed and final rulemaking is appropriate to calculate Factor 1 and consistent with our approach in previous rulemakings. In this final rule, OACT has updated the estimate of Factor 1 with more recent economic assumptions and actuarial analyses.

Comment: Commenters expressed concern regarding the proposed $800 million reduction in the amount available to make uncompensated care payments in FY 2023 compared to FY 2022. Commenters stated that this reduction does not align with CMS' objective to reduce healthcare inequities as the reduction disproportionately impacts safety-net hospitals, which primarily serve low income and vulnerable populations.

Response: The statute specifies that Factor 1 is based on the amount of disproportionate share payments that would otherwise be made to subsection (d) hospitals for the fiscal year. Because our estimate of Factor 1 is based on the best available data regarding the amount of DSH payments that would otherwise be made during FY 2023, we believe it is appropriate and consistent with the requirements of the statute.

After consideration of the public comments we received, we are finalizing, as proposed, the methodology for calculating Factor 1 for FY 2023. We discuss the resulting Factor 1 amount for FY 2023 in this section. For this final rule, OACT used the most recently submitted Medicare cost report data from the March 31, 2022, update of HCRIS to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the Impact File published in conjunction with the publication of the FY 2023 IPPS/LTCH PPS final rule and applied update factors and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

The June 2022 OACT estimate for Medicare DSH payments for FY 2023, without regard to the application of section 1886(r)(1) of the Act, was approximately $13.949 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model, hospitals participating in the Rural Community Hospital Demonstration, and SCHs paid under their hospital-specific payment rate. Therefore, based on this June 2022 estimate, the estimate of empirically justified Medicare DSH payments for FY 2023, with the application of section 1886(r)(1) of the Act, was approximately $3.487 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2023). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two OACT estimates. Therefore, the final Factor 1 for FY 2023 is $10,461,731,029.40, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2023 ($13,948,974,705.87 minus $3,487,243,676.47).

The Office of the Actuary's estimates of DSH expenditures for FY 2023 for this final rule began with a baseline of $13.814 billion in Medicare DSH

expenditures for FY 2019. The following table shows the factors applied to update this baseline through the current estimate for FY 2023:

Factors Applied for FY 2020 through FY 2023 to Estimate Medicare DSH Expenditures Using FY 2019 Baseline						
FY	Update	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)*
2020	1.031	0.862	1.038	0.9952	0.9181	12.682
2021	1.029	0.939	1.029	1.0174	1.0116	12.829
2022	1.025	0.986	0.99	1.0235	1.0241	13.138
2023	1.043	1.050	0.99	0.9793	1.0618	13.949

*Rounded.

In this table, the discharges column shows the changes in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The discharge figures for FY 2020 and FY 2021 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. We note that these claims data reflect the impact of the pandemic. The discharge figure for FY 2022 is based on preliminary data. The discharge figure for FY 2023 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The discharge figures for FY 2020 to FY 2023 incorporate the actual impact and estimated future impact of the COVID–19 pandemic. The case-mix column shows the estimated change in case-mix for IPPS hospitals. The case-mix figures for FY 2020 and FY 2021 are based on actual claims data adjusted by a completion factor. We note that these claims data reflect the impact of the pandemic. The case-mix figure for FY 2022 is based on preliminary data and the case-mix figure for FY 2023 is an assumption based on recent trends recovering back to the long-term trend. The case-mix factor figures for FY 2020 to FY 2023 incorporate the actual impact and estimated future impact of the COVID–19 pandemic. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy and the 20 percent add-on for COVID–19 discharges). In addition, the ''Other'' column includes a factor for the estimated changes in Medicaid enrollment. We note that this factor also includes the estimated impacts on Medicaid enrollment from the COVID–19 pandemic. We note that, based on the most recent available data, Medicaid enrollment is estimated to change as follows: 2.0 percent in FY 2020, 9.5 percent in FY 2021, 4.2 percent in FY 2022, and -5.7 percent in FY 2023. In the future, the assumptions regarding Medicaid enrollment may change based on actual enrollment in the States.

For a discussion of general issues regarding Medicaid projections, we refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid, which is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/MedicaidReport*. We note that, in developing their estimates of the effect of Medicaid enrollment increases on Medicare DSH expenditures, our actuaries have assumed that the increases in the number of Medicaid enrollees result in increases in Medicare DSH expenditures at the same rate as historical relationships have shown. In the future, the assumption about the average per-capita expenditures of Medicaid beneficiaries who enrolled due to the COVID–19 pandemic may change, given that the pandemic is still ongoing.

The following table shows the factors that are included in the ''Update'' column of the previous table:

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Productivity Adjustment	Documentation and Coding	Total Update Percentage
2020	3.0	0	-0.4	0.5	3.1
2021	2.4	0	0	0.5	2.9
2022	2.7	0	-0.7	0.5	2.5
2023	4.1	0	-0.3	0.5	4.3

Note: All numbers are the inpatient hospital updates for the applicable year. We refer readers to section V.A. of the preamble of this final rule for a complete discussion of the changes in the inpatient hospital update for FY 2023.

2. Calculation of Factor 2 for FY 2023

(a) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. In FY 2020 and subsequent fiscal years, there is no longer a reduction. We note that, unlike section 1886(r)(2)(B)(i) of the Act, which governed the calculation of Factor 2 for FYs 2014, 2015, 2016, and 2017, section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65 years of age. We proposed to use a methodology similar to the one that was used in FY 2018 through FY 2022 to determine Factor 2 for FY 2023.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198), we explained that we determined the data source for the rate of uninsurance that, on balance, best meets all of our considerations and is consistent with the statutory requirement that the estimate of the rate of uninsurance be based on data from the Census Bureau or other sources the Secretary determines appropriate, is the uninsured estimates produced by OACT as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has been used to study numerous topics related to the health care sector, including, but not limited to, changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform; and comparisons to other countries' health spending. Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured, because this information is integral to the well-established NHEA methodology. A full description of the methodology used to develop the NHEA is available on the CMS website at *https://www.cms.gov/files/document/definitions-sources-and-methods.pdf*. We note that the NHEA estimates of uninsurance are for the total resident-based U.S. population, including all people who usually reside in the 50 States or the District of Columbia, but excluding individuals living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside the U.S., plus a small (typically less that 0.2 percent of population) adjustment to reflect Census undercounts. Thus, the NHEA estimates of uninsurance are for U.S. residents of all ages and are not limited to a specific age cohort, such as the population under the age of 65. As we explained in the FY 2018 IPPS/LTCH PPS proposed and final rules, we believe it is appropriate to use an estimate that reflects the rate of uninsurance in the U.S. across all age groups. In addition, we continue to believe that a resident-based population estimate more fully reflects the levels of uninsurance in the U.S. that influence uncompensated care for hospitals than an estimate that reflects only legal residents.

The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2020, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2020. The NHEA data are publicly available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*.

In order to compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey (CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. (We refer readers to the website at *https://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at *http://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2018, OACT extrapolates from the 2009 CPS data through 2018 using data from the National Health Interview Survey (NHIS). The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). The 2019 estimate was extrapolated using the 2019/2018 trend from the American Community Survey (ACS). The 2020 estimate was extrapolated using the 2020/2018 trend from the CPS as published by the Census Bureau. The U.S. Census Bureau is the data collection agent for the NHIS, the ACS, and the CPS. The results from these data sources have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC website at *https://www.cdc.gov/nchs/nhis/index.htm*. For further information regarding the ACS, we refer readers to the Census Bureau's website at *https://www.census.gov/programs-surveys/acs/*. For information regarding the data collection issues regarding the 2020 ACS, we refer readers to the Census Bureau's website at *https://www.census.gov/newsroom/blogs/random-samplings/2021/10/pandemic-impact-on-2020-acs-1-year-data.html*. Since the 2020 ACS data

were not available, the ACS data were not used for purposes of estimating the number of uninsured individuals for 2020.

The next metrics needed to compute Factor 2 for FY 2023 are projections of the rate of uninsurance in both CY 2022 and CY 2023. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. The most recent projections are for 2021 through 2030. Those projections use the latest NHEA historical data, available at the time of their construction. The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. The projected growth rates in enrollment for Medicare, Medicaid, and CHIP are developed to be consistent with the 2021 Medicare Trustees Report, updated where possible with more recent data. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on a set of macroeconomic assumptions that are generally based on the 2021 Medicare Trustees Report. Greater detail can be found in OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification,'' which is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*.

(b) Factor 2 for FY 2023

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, using these data sources and the previously described methodologies, OACT estimated that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2022 and 2023 is 8.9 percent and 9.3 percent, respectively. As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified these estimates. We refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for the FY 2023 IPPS/LTCH PPS proposed rule for further details on the methodology and assumptions that were used in the projection of these rates of uninsurance.[213]

As with the CBO estimates on which we based Factor 2 for fiscal years before FY 2018, the NHEA estimates are for a calendar year. Under the approach originally adopted in the FY 2014 IPPS/LTCH PPS final rule, we have used a weighted average approach to project the rate of uninsurance for each fiscal year. We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, we proposed to continue to apply the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2023.

The OACT certified the estimate of the rate of uninsurance for FY 2023 determined using this weighted average approach to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act. In the FY 2023 IPPS/LTCH PPS proposed rule, we noted that we might also consider the use of more recent data that might become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2023. In the proposed rule, we outlined the calculation of the proposed Factor 2 for FY 2023 as follows:

Percent of individuals without insurance for CY 2013: 14 percent.

Percent of individuals without insurance for CY 2022: 8.9 percent.

Percent of individuals without insurance for CY 2023: 9.3 percent.

Percent of individuals without insurance for FY 2023 (0.25 times 0.089) + (0.75 times 0.093): 9.2 percent.

$1 - |((0.092 - 0.14)/0.14)| = 1 - 0.3429 = 0.6571$ (65.71 percent).

For FY 2020 and subsequent fiscal years, section 1886(r)(2)(B)(ii) of the Act no longer includes any reduction to the previous calculation in order to determine Factor 2. Therefore, we proposed that Factor 2 for FY 2023 would be 65.71 percent.

The proposed FY 2023 uncompensated care amount was $9,949,258,556.56 * 0.6571 = $6,537,657,797.52.

Proposed FY 2023 Uncompensated Care Amount	$6,537,657,797.52

In addition, we stated that it had recently come to our attention that the provision of the regulations that addresses Factor 2 inadvertently omits any reference to the statutory methodology in section 1886(r)(2)(B)(ii) of the Act for determining Factor 2 for FY 2018 and subsequent fiscal years. Accordingly, we proposed a technical change to the regulation at § 412.106 to update paragraph (g)(1)(ii) to reflect the statutory requirements governing the determination of Factor 2 for FY 2018 and subsequent fiscal years. We explained that we have determined Factor 2 for FY 2018 through FY 2022 consistent with the plain language of section 1886(r)(2)(B)(ii) of the Act; therefore, this proposed technical change is intended merely to update our regulations to reflect the methodology for determining Factor 2 that has applied since FY 2018 and will continue to apply for FY 2023 and subsequent fiscal years.

We invited public comments on our proposed Factor 2 for FY 2023 and on the proposed technical change to the regulation at § 412.106(g)(1)(ii).

Comment: The majority of commenters discussed Factor 2 in the context of the impact of the temporary COVID–19 PHE provisions, such as the Families First Coronavirus Response Act's Medicaid continuous coverage requirement and the American Rescue Plan's Marketplace enhanced premium tax credits, on the uninsured rate for FY 2023. Commenters questioned CMS' estimates for the FY 2023 uninsured rate and urged the Office of the Actuary (OACT) to update its estimate of Factor 2 to account for the projected increases in the number of uninsured as the COVID–19 PHE provisions expire. Many commenters questioned CMS' estimated decrease in the uninsured rate from 9.6 percent in the FY 2022 IPPS/LTCH PPS final rule to 9.2 percent in FY 2023 IPPS/LTCH PPS proposed rule and stated that they expect increases in the uninsured rates in their communities. Further, many commenters noted that the proposed decrease of $800 million in uncompensated care payments from the level in FY 2022 was likely, in part, driven by the projected uninsured rate. To that end, commenters cited CMS'

[213] OACT Memorandum on Certification of Rates of Uninsured. March 28, 2022. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInPatientPPS/dsh.html*.

statement in the proposed rule that the agency might consider more recent data that may have become available for the calculation of Factor 2 in FY 2023 and urged CMS to use more recent data sources to account for the anticipated increase in the uninsured rate. One commenter requested that CMS consider temporarily changing its methodology for calculating Factor 2 to better account for individuals who may lose their healthcare coverage when various PHE provisions expire and noted that CMS has taken similar approaches in other Medicare payment areas affected by the COVID–19 PHE.

Many commenters referenced various data sources and analyses, such as the Kaiser Family Foundation, the Urban Institute, and HHS' Assistant Secretary for Planning and Evaluation (ASPE) which project 5 to 16 million individuals will lose their Medicaid coverage and another 3 million additional individuals will lose their marketplace insurance in FY 2023. Accordingly, these commenters requested that CMS increase Factor 2 to reflect the anticipated increase in the uninsured population as suggested by these sources. In addition, one commenter requested that CMS exclude FY 2020 and FY 2021 data when calculating the uninsured rate to eliminate any irregularities due to the COVID–19 PHE.

Response: We thank the commenters for their input regarding the estimate of Factor 2 for FY 2023 included in the proposed rule. In response to commenters who requested that we update the estimate of the FY 2023 uninsured rate to fully consider any changes due to the anticipated expirations of the PHE and the Marketplace premium tax credits, we note that the rate of uninsurance used for the calculation of Factor 2 for the proposed rule, as well as for this final rule, reflects CMS' latest analyses and projections. The projected enrollment trends across all insurance types, as well as for the uninsured, take into account the expected impacts of current law including the termination of the Families First Coronavirus Response Act's continuous coverage provision for Medicaid (assumed to expire when the PHE ends in 2022 and to be accompanied by a one-year transition of disenrollments from the program for those no longer eligible) and the conclusion of the enhanced Marketplace premium tax credits. We believe that this NHEA projection, on balance, best meets all of our considerations for ensuring that the data source that underlies the Factor 2 calculation of the uninsured rate meets the statutory requirement that the estimate be based on data sources that the Secretary determines to be appropriate, is certified by CMS' Chief Actuary, and provides a reasonable estimate for the rate of uninsurance that is available in conjunction with the IPPS rulemaking cycle. We refer readers to OACT's memorandum ''Certification of Rates of Uninsured'' and OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification'' for further details on the methodology and updated assumptions used in the calculation of the projected uninsured rate.

We disagree with comments' suggestions that we exclude FY 2020 and FY 2021 data, or any data from the COVID–19 PHE period, for purposes of calculating the uninsured rate for FY 2023. The projections that underlie the FY 2023 Factor 2 calculation should take into consideration, and include, those elements that are expected to influence health insurance enrollment trends during FY 2023, and the resulting rate of uninsured, including the unique circumstance associated with the COVID–19 pandemic.

Comment: Some commenters suggested that CMS use a different estimate of the uninsured rate to calculate Factor 2 for FY 2023, while acknowledging that OACT accounted for the expiration of the COVID–19 PHE provisions in its uninsurance estimates. These commenters indicated that because the uninsured percent change serves as a proxy for the change in the amount of uncompensated care that hospitals provide, it would be appropriate for CMS to apply a case-mix adjuster to the uninsured rate for FY 2023 to account for the rise in resources that will be used by hospitals to provide care to uninsured individuals who may have delayed their care during the COVID–19 PHE.

A few commenters requested that CMS maintain the same level of uncompensated care funding as in FY 2022 ($7.2 billion) while another commenter requested that CMS consider delaying any proposed changes to the uncompensated care payment calculations until analyses can be performed to determine the actual uninsured rate and related costs following the end of the COVID–19 PHE. Other commenters urged CMS to be transparent in its calculation of Factor 2 and how it accounts for Medicaid expansion populations, while others urged CMS to be transparent regarding the data sources used for calculating Factor 2 and the assumptions behind the uninsured rate.

Response: Regarding the commenters that requested modifications to the uninsured rate, such as multiplying by a case-mix factor, we note that these recommendations would not be consistent with the statutory requirements in section 1886(r)(2)(B)(ii). The statute explicitly specifies that Factor 2 be based on 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 and the percent of individuals who were uninsured in the most recent period for which data are available.

Regarding the comments recommending that CMS maintain total uncompensated care payments at the FY 2022 level or delay any changes to the amount available to make uncompensated care payments, we believe estimating Factor 2 based on the best available data regarding the expected rate of uninsurance in FY 2023 is appropriate and consistent with the statute.

In response to the comments concerning transparency, we reiterate that we have been and continue to be transparent with respect to the methodology and data used to estimate Factor 2. The FY 2023 IPPS/LTCH PPS proposed rule included a detailed discussion of our proposed Factor 2 methodology, as well as the data sources that would be used in making our final estimate. For purposes of this final rule, we are using projected rates of uninsurance for CY 2022 and CY 2023, which account for the effects of the COVID–19 PHE and any legislative impacts arising from the end of the COVID–19 PHE on insurance coverage. Section 1886(r)(2)(B)(ii) of the Act permits us to use a data source other than CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. We continue to believe that the NHEA data and methodology used to estimate Factor 2 are transparent and best meet all of our considerations for ensuring reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. Accordingly, we continue to believe that it is appropriate to calculate Factor 2 based on the NHEA-based projection of the FY 2023 rate of uninsurance as we proposed.

After consideration of the public comments we received, we are finalizing, as proposed, the Factor 2 calculation for FY 2023. The estimates of the percent of uninsured individuals were produced and certified by OACT for purposes of the FY 2023 IPPS proposed rule. Those published CY and

estimated FY rates continue to be the latest available projections.

The calculation of the final Factor 2 for FY 2023 using a weighted average of OACT's certified estimates is as follows:

Percent of individuals without insurance for CY 2013: 14 percent.

Percent of individuals without insurance for CY 2022: 8.9 percent.

Percent of individuals without insurance for CY 2023: 9.3 percent.

Percent of individuals without insurance for FY 2023 (0.25 times 0.089) + (0.75 times 0.093): 9.2 percent.

$1 - |((0.092 - 0.14)/0.14)| = 1 - 0.3429 = 0.6571$ (65.71 percent).

Therefore, the final Factor 2 for FY 2023 is 65.71 percent. The final FY 2023 uncompensated care amount is $10,461,731,029.40* 0.6571 = $6,874,403,459.42.

Final FY 2023 Uncompensated Care Amount	$ 6,874,403,459.42

We did not receive any comments on our proposed technical change to the regulation governing the calculation of Factor 2. We are finalizing the update to § 412.106(g)(1)(ii), as proposed.

3. Calculation of Proposed Factor 3 for FY 2023

(a) General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) the definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, the first year for which section 1886(r) of the Act was in effect, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and determined that Worksheet S–10 of the Medicare cost report would potentially provide the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not use Worksheet S–10 data to determine Factor 3 for FY 2014, or for FYs 2015, 2016, or 2017. Instead, we used alternative data on the utilization of insured low-income patients, as measured by patient days, which we believed would be a better proxy for the costs of hospitals in treating the uninsured and therefore appropriate to use in calculating Factor 3 for these years. Of particular importance in our decision to use proxy data was the relative newness of Worksheet S–10, which went into effect on May 1, 2010. At the time of the rulemaking for FY 2014, the most recent available cost reports would have been from FYs 2010 and 2011 and submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. However, we indicated our belief that Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals were submitting more accurate and consistent data through this reporting mechanism.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38202), we stated that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10, conducted both internally and by stakeholders, demonstrating that Worksheet S–10 accuracy had improved over time. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through 38203) for a complete discussion of these analyses.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38206), we recognized commenters' concerns that, in continuing to use Medicaid days as part of the proxy for uncompensated care, it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. In the FY 2018 IPPS/LTCH PPS final rule, we finalized a methodology under which we calculated Factor 3 for all eligible hospitals, with the exception of Puerto Rico hospitals and Indian Health Service (IHS) and Tribal hospitals, using Worksheet S–10 data from FY 2014 cost

reports in conjunction with low-income insured days proxy data based on Medicaid days and SSI days. The time period for the Medicaid days data was FY 2012 and FY 2013 cost reports, which reflected the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid (82 FR 38208 through 38212).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41414), we stated that with the additional steps we had taken to ensure the accuracy and consistency of the data reported on Worksheet S–10 since the publication of the FY 2018 IPPS/LTCH PPS final rule, we continued to believe that we could no longer conclude that alternative data to the Worksheet S–10 were currently available for FY 2014 or FY 2015 that would be a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41428), we advanced the time period of the data used in the calculation of Factor 3 forward by 1 year and used Worksheet S–10 data from FY 2014 and FY 2015 cost reports in combination with the low income insured days proxy for FY 2013 to determine Factor 3 for FY 2019. We note that, as discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42366), the use of 3 years of data to determine Factor 3 for FY 2018 and FY 2019 had the effect of smoothing the transition from the use of low-income insured days to the use of Worksheet S–10 data.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41424), we received overwhelming feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10. We began auditing the Worksheet S–10 data for selected hospitals in the Fall of 2018 so that the audited uncompensated care data from these hospitals would be available in time for use in the FY 2020 IPPS/LTCH PPS proposed rule.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42368), we finalized our proposal to use a single year of audited Worksheet S–10 cost report data from FY 2015 in the methodology for determining Factor 3 for FY 2020. Although some commenters expressed support for the alternative policy of using the more recent FY 2017 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2020, given the feedback from commenters in response to both the FY 2019 and FY 2020 IPPS/LTCH PPS proposed rules, emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we concluded that the FY 2015 Worksheet S–10 data were the best available audited data to be used in determining Factor 3 for FY 2020. We also noted that we had begun auditing the FY 2017 data in July 2019, with the goal of having the FY 2017 audited data available for future rulemaking.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58823 through 58825), we finalized our proposal to use the most recent available single year of audited Worksheet S–10 data to determine Factor 3 for FY 2021 and subsequent fiscal years. We explained our belief that using the most recent audited data available before the applicable Federal fiscal year, will more accurately reflect a hospital's uncompensated care costs, as opposed to averaging multiple years of data. We explained that mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result. We also noted that if a hospital has relatively different data between cost report years, we potentially would be diluting the effect of our considerable auditing efforts and introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3. Therefore, we also believed using a single year of audited cost report data would be an appropriate methodology to determine Factor 3 for FY 2021 and subsequent years, except for IHS and Tribal hospitals and hospitals located in Puerto Rico. For IHS and Tribal hospitals and Puerto Rico hospitals, we finalized the use of a low-income insured days proxy to determine Factor 3 for FY 2021. We did not finalize a methodology to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals for FY 2022 and subsequent years because we believed further consideration and review of these hospitals' Worksheet S–10 data was necessary (85 FR 58825).

In the FY 2021 IPPS/LTCH PPS final rule, we finalized the definition of ''uncompensated care'' for FY 2021 and subsequent fiscal years, for purposes of determining uncompensated care costs and calculating Factor 3 (85 FR 58825 through 58828). Specifically, ''uncompensated care'' is defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29). This is the same definition that we initially adopted in the FY 2018 IPPS/LTCH PPS final rule. We refer readers to the FY 2021 IPPS/LTCH PPS rule (85 FR 58825 through 58828) for a discussion of additional topics related to the definition of uncompensated care. We noted in the FY 2021 IPPS/LTCH PPS final rule that the Paper Reduction Act (PRA) package for Form CMS–2552–10 would offer an additional opportunity to comment on the cost reporting instructions. A PRA package with comment period appeared in the November 10, 2020, **Federal Register** (85 FR 71653). We thank stakeholders for their comments on the PRA package. For further information, we refer the readers to the following website. *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202206-0938-017.*

(b) Background on the Methodology Used To Calculate Factor 3 for FY 2022

Section 1886(r)(2)(C) of the Act governs both the selection of the data to be used in calculating Factor 3, and also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for a subsection (d) hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2022 IPPS/LTCH PPS final rule, we continued to apply the following policies as part of the Factor 3 methodology: (1) the policy regarding newly merged hospitals that was initially adopted in the FY 2015 IPPS/LTCH PPS final rule; (2) the policies regarding annualization and long cost reports that were adopted in the FY

2018 and FY 2019 IPPS/LTCH PPS final rules, including a modified policy for the rare cases where a provider has no cost report for the fiscal year that is used in the Factor 3 methodology because the cost report for the previous fiscal year spans both years; (3) the modified new hospital policy that was finalized in the FY 2020 IPPS/LTCH PPS final rule; (4) the new merger policy adopted in the FY 2021 IPPS/LTCH PPS final rule that accounts for the merger effective date; and (5) the policies regarding the application of statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10. We discuss these policies in greater detail in this section.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45244), we continued to treat hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule, for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year would be recalculated similar to new hospitals (79 FR 50021 and 50022). Consistent with past policy, interim uncompensated care payments for newly merged hospitals are based only on the data for the surviving hospital's CCN available at the time of the development of the final rule. However, at cost report settlement, we will determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its cost report for the applicable fiscal year. That is, for FY 2022, we will revise the numerator of Factor 3 for a newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2022 cost report.

In FY 2022 IPPS/LTCH PPS final rule, we continued the policy that was finalized in the FY 2018 IPPS/LTCH PPS final rule of annualizing uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data, except in the case of mergers, which would be subject to the modified merger policy originally adopted in FY 2021. In addition, we continued the policies that were finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41415) regarding the use of the longest cost report available within the Federal fiscal year. We also applied the modified policy that was adopted in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58829) for those rare situations where a hospital has a cost report that starts in one fiscal year but spans the entirety of the following fiscal year such that the hospital has no cost report starting in that subsequent fiscal year. Under this modified policy, we use the cost report that spans both fiscal years for purposes of calculating Factor 3 when data from the latter fiscal year are used in the Factor 3 methodology.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 25454), we continued the modified new hospital policy for new hospitals that do not have data for the cost reporting period(s) used in the Factor 3 calculation (that is, the most recent cost reporting year for which audits have been conducted). Under the modified policy originally adopted for FY 2020, new hospitals that have a preliminary projection of being eligible for Medicare DSH based on their most recent available disproportionate patient percentages may receive interim empirically justified DSH payments during the fiscal year. However, because these hospitals do not have a cost report for the cost reporting period used in the Factor 3 calculation and the projection of eligibility for DSH payments is still preliminary, we are unable to calculate a prospective Factor 3 for these hospitals and they do not receive interim uncompensated care payments. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments for the fiscal year at cost report settlement. Thus, for FY 2022, if a new hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2022, the hospital will receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2022 cost report, and the denominator is the same denominator that was used in the prospective Factor 3 calculation for FY 2022 (that is, the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2018 cost reports for all DSH-eligible hospitals).

In the FY 2022 IPPS/LTCH PPS final rule, we continued the new merger policy that accounts for the merger effective date, that was originally adopted in FY 2021. To more accurately estimate uncompensated care costs (UCC) for the hospitals involved in a merger when the merger effective date occurs partway through the surviving hospital's cost reporting period, we apply a policy of not annualizing the acquired hospital's data. Under this policy, we use only the portion of the acquired hospital's unannualized UCC data that reflects the UCC incurred prior to the merger effective date, but after the start of the surviving hospital's current cost reporting period. To do this, we calculate a multiplier to be applied to the acquired hospital's UCC. This multiplier represents the portion of the UCC data from the acquired hospital that should be incorporated with the surviving hospital's data to determine UCC for purposes of determining Factor 3 for the surviving hospital. This multiplier is obtained by calculating the number of days between the start of the applicable cost reporting period for the surviving hospital and the merger effective date, and then dividing this result by the total number of days in the reporting period of the acquired hospital. Applying this multiplier to the acquired hospital's unannualized UCC data will determine the final portion of the acquired hospital's UCC that should be added to the UCC of the surviving hospital for purposes of determining Factor 3 for the merged hospital.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 25454 and 25455), we continued to apply a CCR trim methodology similar to the CCR trim methodology policy that has been used for purposes of determining uncompensated care payments since FY 2018. This CCR trim methodology is consistent with the approach used in the outlier payment methodology under § 412.84(h)(3)(ii), which states that the Medicare contractor may use a statewide average CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean. We refer readers to the discussion in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831) for a detailed description of the steps used to determine the applicable CCR.

In addition, we continued the UCC data trim methodology for rare situations where a hospital has potentially aberrant data that are unrelated to its CCR (86 FR 45245). However, because we audit the Worksheet S–10 data for a number of hospitals, we no longer believe it is necessary to apply the trim methodology for hospitals whose cost report has been audited. Accordingly, for FY 2022, we continued the policy adopted in FY 2021 under which we exclude hospitals that were part of the audits for the fiscal year used in the Factor 3 calculation from the trim

methodology for potentially aberrant UCC. We also continued to apply a modified trim methodology for all-inclusive rate providers (AIRPs) with potentially aberrant UCC (86 FR 45235). Under this modified trim methodology, when an AIRP's total UCC are greater than 50 percent of its total operating costs when calculated using the CCR included on its cost report for the most recent cost reporting year for which audits have been conducted, we recalculate the AIRP's UCC using the CCR reported on Worksheet S–10, line 1 of the hospital's most recent available prior year cost report that does not result in UCC of over 50 percent of total operating costs.

In addition, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45245 and 452456), we finalized an alternative trim specific to hospitals that are not projected to be DSH-eligible and that do not have audited FY 2018 Worksheet S–10 data for use in determining Factor 3. We explained that we believe this new alternative trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the existing trim, because the existing trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs. Specifically, we finalized that, for the hospitals that would be subject to the trim, if the hospital is ultimately determined to be DSH-eligible at cost report settlement, then the MAC would calculate a Factor 3 after reviewing the uncompensated care information reported on Worksheet S–10 of the hospital's FY 2022 cost report. We stated that we believe if a hospital subject to this trim is ultimately determined to be DSH-eligible at cost report settlement, its uncompensated care payment should be calculated only after the hospital's reporting of insured charity care costs on its FY 2022 Worksheet S–10 has been reviewed. We noted that this approach is comparable to the policy for new hospitals for which we cannot calculate a prospective Factor 3 because they do not have Worksheet S–10 data for the relevant fiscal year.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45242 and 45243), we continued the policy we first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S–10 data when determining Factor 3 for IHS and Tribal hospitals and subsection (d) Puerto Rico hospitals that have a FY 2013 cost report. We stated our belief that this approach was appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In addition, because we continued to use 1 year of insured low income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we continued to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45236) for a discussion of the approach that we continued to apply in FY 2022 to determine Factor 3 for new Puerto Rico hospitals. In brief, Puerto Rico hospitals that do not have a FY 2013 cost report were considered new hospitals and subject to the new hospital policy, as discussed previously. Specifically, the numerator of the Factor 3 calculation will be the uncompensated care costs reported on Worksheet S–10 of the hospital's cost report for the applicable fiscal year and the denominator is the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals.

Consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule and codified in the regulations at § 412.106(g)(8) for subsequent fiscal years, in the FY 2022 IPPS/LTCH PPS final rule we used a single year of Worksheet S–10 data from FY 2018 cost reports to calculate Factor 3 for FY 2022 for all eligible hospitals with the exception of IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013.

Therefore, for FY 2022, we applied the following methodology to compute Factor 3 for each hospital:

Step 1: Select the provider's longest cost report from its Federal fiscal year (FFY) 2018 cost reports. (Alternatively, in the rare case when the provider has no FFY 2018 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2018 time period, the previous Federal fiscal year cost report will be used in this step.)

Step 2: Annualize the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

Step 4: Calculate Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013 using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals.

Step 5: Calculate Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2018 cost report data (from Step 1, 2 or 3). New hospitals and the hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

In the FY 2022 IPPS/LTCH PPS final rule, we amended the regulation at § 412.106 by adding a new paragraph (g)(1)(iii)(C)(*9*) to reflect the methodology for computing Factor 3 for FY 2022 for IHS and Tribal hospitals and for Puerto Rico hospitals that have a 2013 cost report. We also finalized a conforming change to limit the reference to Puerto Rico hospitals in § 412.106(g)(1)(iii)(C)(*8*) to those Puerto Rico hospitals that have a cost report for 2013.

(c) Changes to the Methodology for Calculating Factor 3 for FY 2023 and Subsequent Fiscal Years

As described in the FY 2022 IPPS/LTCH PPS final rule, commenters expressed concerns that the use of only 1 year of data to determine Factor 3 would lead to significant variations in year-to-year uncompensated care payments. Some stakeholders recommended the use of 2 years of historical Worksheet S–10 data (86 FR 45237). In the FY 2022 IPPS/LTCH PPS final rule, we stated that we would consider using multiple years of data when the vast majority of providers have been audited for more than 1 fiscal year under the revised reporting instructions. The audits of FY 2019 cost reports began in 2021 and those audited reports were available in time for the development of the FY 2023 IPPS/LTCH PPS proposed rule. Feedback from previous audits and lessons learned were incorporated into the audit process for the FY 2019 reports.

In consideration of the comments discussed in the FY 2022 IPPS/LTCH PPS final rule, in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to determine Factor 3 for FY 2023 using the average of the audited FY 2018 and audited FY 2019 reports. We stated our belief that this proposal would address concerns from stakeholders regarding

year-to-year fluctuations in uncompensated care payments. In addition, taking into consideration the comments recommending that CMS transition to the use of 3 years of audited data, we indicated that we expect FY 2024 will be the first year that 3 years of audited data will be available at the time of rulemaking. Accordingly, for FY 2024 and subsequent fiscal years, we proposed to use a 3-year average of the uncompensated care data from the 3 most recent fiscal years for which audited data are available to determine Factor 3. Specifically, for FY 2024, we would expect to use data from FY 2018, FY 2019, and FY 2020 reports to calculate uncompensated care payments. In other words, for each of the 3 most recent fiscal years for which audited data are available at the time of rulemaking for the applicable fiscal year, we would divide a hospital's uncompensated care costs for the fiscal year by the estimated total uncompensated care costs of all DSH hospitals for that fiscal year. Then, we would calculate an average of those proportions to determine the hospital's Factor 3 for the applicable Federal fiscal year. We explained that we believe the proposed approach is generally consistent with our past practice of using the most recent single year of audited data from the Worksheet S–10, while also addressing commenters' concerns regarding year-to-year fluctuations in uncompensated care payments. Consistent with the approach that we followed when multiple years of data were previously used in the Factor 3 methodology, we proposed that if a hospital does not have data for all 3 years used in the Factor 3 calculation, we would determine Factor 3 based on an average of the hospital's available data.

We invited public comments on our proposed methodology for calculating Factor 3 for FY 2023 and subsequent fiscal years, including, but not limited to, our proposal to use the most recent audited Worksheet S–10 data from FY 2018 and FY 2019 cost reports to determine Factor 3 for FY 2023, and our proposal to begin using the 3 most recent years of audited Worksheet S–10 data starting in FY 2024.

Comment: Commenters expressed continued support for the general use of Worksheet S–10 data to calculate each hospital's share of uncompensated care costs in FY 2023 and future years. Some commenters also noted their long-standing support for using audited Worksheet S–10 data to promote an accurate and consistent calculation of uncompensated care costs. One commenter, who supported using Worksheet S–10 data, stressed the importance of ongoing refinements to the audit process to ensure data accuracy, while another recommended that CMS regularly assess and identify unusual or irregular trends in the data.

Response: We appreciate the support for our proposal to use Worksheet S–10 data to calculate Factor 3 for FY 2023 and future years. Regarding those comments that noted the importance of ongoing refinements to the Worksheet S–10 audit process, we reiterate our commitment to continue working with the MACs and providers on audit improvements, including changes to increase the efficiency of the audit process and build on the lessons learned in previous audit years. As noted in the FY 2023 IPPS/LTCH PPS proposed rule, we believe that, on balance, Worksheet S–10 data are the best available data to use for calculating Factor 3 for FY 2023 and subsequent fiscal years.

Comment: An overwhelming majority of commenters expressed support for CMS' proposal to calculate Factor 3 for FY 2023 based on a two-year average of audited FY 2018 and FY 2019 Worksheet S–10 data. These commenters also expressed support for the proposal to transition to use of a three-year average of the most recent available audited Worksheet S–10 data for FY 2024 and subsequent fiscal years. Some commenters explicitly stated that they agreed with CMS that the use of only one year of data could lead to undue fluctuations in year-to-year uncompensated care payments. Supporters of these proposals also specified several benefits from the use of a multi-year average of Worksheet S–10 data, such as minimizing year-to-year volatility, ensuring stability in future uncompensated care payments, and mitigating the effect of irregular trends and data anomalies, like the COVID–19 PHE. One commenter suggested that CMS consider working with hospitals in future years to ensure that Worksheet S–10 data from the COVID–19 PHE period is reported appropriately, given the PHE's significant impact on the utilization of healthcare services. To this end, one commenter recommended that CMS consider incorporating FY 2020 Worksheet S–10 data into the multi-year average for FY 2023 once the data has been audited, as this approach would be more reflective of current healthcare costs.

In contrast, only a handful of commenters expressed opposition to using a two-year average of audited FY 2018 and FY 2019 Worksheet S–10 data for FY 2023 and a three-year average of Worksheet S–10 data to calculate uncompensated care payments moving forward. One commenter indicated that using a three-year average to calculate FY 2024 uncompensated care payments would dilute the impact of the COVID–19 PHE on the FY 2020 Worksheet S–10 data. This commenter asserted that using a multi-year average would benefit hospitals that received the highest amount of Health Resources & Services Administration (HRSA) subsidies and hospitals with lower uncompensated care costs, while harming hospitals with higher uncompensated care cost data in FY 2020. The commenter also requested that CMS provide expedited procedures for reopening and correcting Worksheet S–10 data for the cost reporting periods that will be used to calculate uncompensated care payments in FY 2024 and future years.

Another commenter noted that the FY 2022 methodology based on one year of audited Worksheet S–10 data was adequate and should not be modified to a multi-year average, indicating that inconsistencies in the methodology used to calculate Factor 3 from year to year add a further burden to hospitals' ability to understand and predict their uncompensated care payments. This commenter also urged CMS to reexamine the continued use of FY 2018 Worksheet S–10 data to determine payments for FY 2022, FY 2023, and FY 2024, as it may benefit hospitals that provided elevated levels of uncompensated care in FY 2018, and negatively impact those that provided less uncompensated care.

Finally, some commenters suggested alternative approaches to calculating Factor 3 of the uncompensated care payment calculation that went beyond the blending of historical Worksheet S–10 data for multiple fiscal years.

Response: We thank commenters who expressed their support for our proposal to use a two-year average of audited FY 2018 and FY 2019 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2023 and to use of a 3-year average of audited Worksheet S–10 data starting in FY 2024. As explained in the FY 2023 IPPS/LTCH PPS proposed rule, we believe that using a multi-year average of Worksheet S–10 data will provide assurance that hospitals' uncompensated care payments remain stable and predictable and will not be subject to unpredictable swings and anomalies in a hospital's uncompensated care costs.

We also believe that our proposal to use multiple years of data is responsive to past commenters' requests for the use of multiple years of audited data. We disagree with the commenter who stated

that modifying the uncompensated care payment methodology to use multiple years of data would put undue burden on a hospital's ability to understand, budget, and forecast as we believe that our proposal to use a multi-year average of Worksheet S–10 data to determine Factor 3 for FY 2023 and subsequent fiscal years is responsive to past recommendations for smoothing fluctuations.

In relation to the commenter who noted that the multi-year average will benefit hospitals that received the highest amount of HRSA subsidies and hospitals with lower uncompensated care costs, we note that cost reporting data from the COVID–19 PHE time period is not yet available to be analyzed. We believe it would be premature to attempt, in this rulemaking, to modify the methodology for determining uncompensated care payments for a future year, specifically to address the potential impact of the PHE-related subsidies.

In response to the request that we provide expedited procedures for reopening and correcting Worksheet S–10 data that will be used in the Factor 3 calculation, we note that we do not intend to establish fixed timelines for reopenings across MACs, so we can retain the flexibility to use our limited audit resources to address and prioritize audit needs across all CMS programs each year. However, we note that MACs work closely with hospitals regarding reopenings.

Regarding commenters' suggestions for alternative approaches to calculating Factor 3 beyond the previously considered methodological concepts for the blending of historical Worksheet S–10 data, we appreciate commenters' input and note that we may consider these suggestions in future rulemaking.

After consideration of the comments received, we are finalizing our proposal to use a two-year average of audited FY 2018 and FY 2019 Worksheet S–10 data to calculate Factor 3 in FY 2023 and a three-year average of audited data from the most recent fiscal years for which audited data are available to determine Factor 3 in subsequent years. We also note that the number of audited hospitals continues to increase year to year and, as a result, we believe data from Worksheet S–10 will improve in reliability over time. However, we will continue to audit additional years of the Worksheet S–10 data and monitor the stability of uncompensated care payments as we move forward with using a multi-year average of audited Worksheet S–10 data for Factor 3 calculations.

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, we have determined Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals, based on the low-income insured days proxy for uncompensated care costs. In the FY 2022 IPPS/LTCH PPS final rule, we discussed comments we had received from IHS/Tribal hospitals and Puerto Rico hospitals about the significant challenges they face in relation to uncompensated care reporting (86 FR 45242 and 45243). For example, a commenter stated that the information technology systems used by IHS and Tribal hospitals are not equipped to collect the necessary data for the Worksheet S–10, noting that while IHS recently received funding to upgrade its information technology system, it will take some time, potentially years, before it is fully functional (86 FR 45242). Another commenter expressed concerns that Puerto Rico hospitals were understating the components of uncompensated care costs, and indicated that technical education is needed to address the challenges Puerto Rico hospitals have regarding charity care and bad debt reporting, which the commenter stated would take years to address (86 FR 45243).

In the FY 2023 IPPS/LTCH PPS proposed rule, we acknowledged that to the extent commenters have identified specific challenges for IHS/Tribal hospitals and Puerto Rico hospitals in reporting uncompensated care costs on Worksheet S–10, it is possible that after a sufficient number of years these reporting challenges could be addressed. However, despite the reporting challenges described by commenters, we expressed our concern that the historical 2013-based data on low-income insured days, which has been used as an alternative to data on uncompensated care costs from the Worksheet S–10 to determine Factor 3 for IHS/Tribal hospitals and Puerto Rico hospitals, is no longer a good proxy for the costs of these hospitals in treating the uninsured, given the time that has elapsed since 2013. In 2023, this data will be 10 years old and there is no obvious way to update the information given our stated concerns surrounding the differential impact of state Medicaid expansions after 2013. In light of these concerns, we stated that we could no longer conclude that alternative data to the data on uncompensated care costs reported on Worksheet S–10 are currently available for IHS/Tribal hospitals and Puerto Rico hospitals that are a better proxy for the costs of these hospitals in treating the uninsured. Accordingly, for FY 2023 and subsequent fiscal years, we proposed to discontinue the use of low-income insured days as a proxy for the uncompensated care costs of these hospitals and proposed to use the same data to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals as for other hospitals. Specifically, for FY 2023, we would determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals based on the average of the uncompensated care data reported on Worksheet S–10 of their FY 2018 and FY 2019 cost reports. However, we sought comments on alternatives both to our proposal to use data on uncompensated care costs from the Worksheet S–10 to determine Factor 3 for IHS/Tribal hospitals and Puerto Rico hospitals and to the continued use of low-income insured days as a proxy for the uncompensated care costs of these hospitals. We also sought comments on how to best measure and define the uncompensated care costs associated with these hospitals that might not otherwise be captured in Factor 3 calculations based on Worksheet S–10 data. Because we recognized that our proposal to discontinue the use of the low-income insured days proxy and to rely solely on Worksheet S–10 data to calculate Factor 3 of the uncompensated care payment methodology for IHS/Tribal hospitals and Puerto Rico hospitals could result in a significant financial disruption for these hospitals, we also proposed to establish a new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals, beginning in FY 2023. We refer readers to section IV.E. of the preamble of this final rule for a complete discussion of this proposed new supplemental payment.

Prior to the proposed rulemaking for FY 2023, CMS consulted with IHS and Tribes regarding our policies for determining uncompensated care payments. They expressed that uncompensated care payments are critical to the providers and should be maintained at their current levels, at a minimum. As we explained in the FY 2023 IPPS/LTCH PPS proposed rule, we considered this recent input along with previous input from stakeholders in the development of our proposed policies. We also welcomed additional input from stakeholders regarding the unique circumstances of IHS/Tribal hospitals and Puerto Rico hospitals and/or any mitigating factors, and noted that this input would inform our considerations about our proposal to determine Factor 3 for these hospitals using data from

Worksheet S–10 and the related proposal to establish a new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

We received comments on our proposal to discontinue the use of the low-income insured days proxy and to rely solely on Worksheet S–10 data to calculate Factor 3 of the uncompensated care payment methodology for IHS/Tribal hospitals and Puerto Rico hospitals. Due to the close interrelationship between this proposal and our proposal to establish a new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals, we discuss those comments, along with the comments received on the proposed new supplemental payment, and set forth our final policies in Section IV.E of this final rule.

For purposes of the FY 2023 proposed rule, we used the December 2021 HCRIS extract to calculate Factor 3. We noted that we intended to use the March 2022 update of HCRIS to calculate Factor 3 for the FY 2023 IPPS/LTCH PPS final rule. However, we stated that we may consider the use of more recent data that may become available after March 2022, but prior to the development of the final rule, if appropriate, for purposes of calculating the final Factor 3 for this FY 2023 IPPS/LTCH PPS final rule.

We received comments regarding the uncompensated care costs definition and Worksheet S–10 cost report instructions.

Comment: With regard to the definition of uncompensated care, several commenters urged CMS to include unreimbursed costs (shortfalls) from Medicaid in the definition of uncompensated care. Specifically, some commenters urged CMS to account for Medicaid shortfalls and incorporate Line 31 of Worksheet S–10 along with already-utilized Line 30. In contrast, one commenter agreed with CMS that Medicaid shortfalls, as currently reported on Worksheet S–10, should not be included in the estimation of uncompensated care costs. Instead, the commenter recommended that the agency revise Worksheet S–10 so data on Medicaid shortfalls better resemble actual shortfalls incurred by hospitals. The commenter further noted that such data will be increasingly useful for informational purposes as previously uninsured individuals gain access to Medicaid. Other commenters proposed incorporating social determinants of health methodologies into uncompensated care costs by including variables that describe socioeconomic disadvantage such as accounting for costs incurred by hospitals to improve access to healthy foods, transportation, health screenings, technology assistance, and similar community needs. Notably, another commenter suggested that CMS redefine uncompensated care to align with the definitions used to determine community benefit spending under the Internal Revenue Code.

Response: We appreciate commenters' suggestions for revisions and/or modifications to Worksheet S–10. We will consider the concerns raised by commenters as part of future cost report clarifications and will make modifications as necessary to further improve and refine the information that is reported on Worksheet S–10 to support collection of the information necessary to implement section 1886(r)(2) of the Act.

With regard to the comments requesting that payment shortfalls from Medicaid be included in uncompensated care cost calculations, we continue to believe there are compelling arguments for excluding such shortfalls from the definition of uncompensated care. First, we note that we did not propose any changes to the definition of uncompensated care costs, which was first adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38215 through 38217) as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29). Additionally, key interested parties (including MedPAC) do not consider Medicaid shortfalls in their definition of uncompensated care. Furthermore, we continue to believe that it is most consistent with section 1886(r)(2) of the Act for Medicare uncompensated care payments to target hospitals that incur a disproportionate share of uncompensated care for patients with no insurance coverage. We also note that even if we agreed that it would be appropriate to adjust the definition of uncompensated care to include Medicaid shortfalls, this would not be a feasible option at this time due to computational limitations. Specifically, computing such shortfalls is operationally problematic because Medicaid pays hospitals a single DSH payment that, in part, covers the hospital's costs for providing care to the uninsured and in part covers estimates of the Medicaid ''shortfalls.'' Therefore, it is not clear how CMS would determine how much of the ''shortfall'' is left after the Medicaid DSH payment is made. In addition, in some States, hospitals return a portion of their Medicaid revenues to the State via provider taxes and receive supplemental payments in return (along with the federal match), making the computation of ''shortfalls'' even more complex.

Regarding the request that we include costs incurred by hospitals to address social determinants of health in the definition of uncompensated care costs, we have consistently stated in past final rules (85 FR 58826 and 86 FR 45239) in response to similar comments that we believe the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured, not for other costs incurred, including costs associated with addressing social determinants of health, as commenters have suggested. Accordingly, we do not believe changing the calculation of uncompensated care costs is appropriate, at this time.

Comment: Commenters requested that CMS include all patient care costs when calculating the cost-to-charge ratio (CCR) used in Worksheet S–10 and urged CMS to include costs incurred for graduate medical education (GME), costs of paying provider taxes associated with Medicaid revenue, and costs of providing physician and other professional services when calculating the CCR used to determine uncompensated care costs on Worksheet S–10 in order to improve the accuracy of that CCR.

Response: As we have stated in past rules (84 FR 42378, 85 FR 58826, and 86 FR 45239) in response to similar requests that we modify the CCR used on Worksheet S–10, we continue to believe the CCR calculation that is used in Worksheet S–10 is appropriate. Regarding the request that we include GME costs, costs of paying provider taxes associated with Medicaid revenue, and costs of providing physician and other professional service when calculating CCR used in Worksheet S–10, we note that because the CCR on Line 1 of Worksheet S–10 is obtained from Worksheet C, Part I, and is also used in other IPPS rate setting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights) from which it is appropriate to exclude the costs associated with supporting GME costs and the costs of physician and professional services and costs of paying provider taxes, we remain reluctant to adjust CCRs in the narrower context of calculating uncompensated care costs. Therefore, as stated in past final rules, we continue to believe that it is not appropriate, at this time, to modify the calculation of the CCR on Line 1 of Worksheet S–10 to include any additional costs in the numerator of the CCR calculation.

Comment: One commenter stated that large teaching hospitals (with 100+

residents) would experience an even larger uncompensated care payment reduction, resulting in underserved and vulnerable populations having less access to transplant programs (as these programs are often operated by large teaching institutions). Another commenter expressed concern that hospitals in Medicaid non-expansion states depend greatly on uncompensated care payments for financial support, and this commenter urged CMS to work with providers and patient advocates in non-expansion states to screen patients for eligibility under either financial assistance policies or premium support under the Affordable Care Act before classifying the case as uncompensated care. The same commenter noted that the equal weighting of bad debt and charity care on the Worksheet S–10 disincentivizes hospitals from ensuring that eligible patients receive charity care, as obtaining the qualification for charity care entails long administrative processes.

Response: We thank commenters for their continued concern regarding the distribution of uncompensated care payments and the impact of reductions in uncompensated care payments on teaching hospitals. However, as stated previously, the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured. Uncompensated payments are not intended to provide support for other activities that hospitals may undertake. We also note that CMS does not set charity care criteria for hospitals, and within reason, hospitals can establish their own criteria of what constitutes charity care in their financial assistance policies.

Comment: With regard to Worksheet S–10 instructions and guidance, a few commenters commended CMS for its efforts to provide clearer instructions for Worksheet S–10. A few commenters requested that CMS clarify inconsistent Worksheet S–10 instructions so that non-Medicare bad debt is not multiplied by the CCR. These commenters noted that CMS' revised instructions indicate that non-reimbursed Medicare bad debt is not reduced by the CCR, but that CMS' September 2017 transmittal states that non-Medicare bad debt should be multiplied by the CCR. One commenter indicated that such practice is inconsistent with the way non-reimbursable Medicare bad debt is treated.

Response: We appreciate commenters' concerns regarding the need for clarification of the Worksheet S–10 instructions, as well as their suggestions for revisions to improve reporting. We reiterate our commitment to continuing to work with impacted parties to address their concerns regarding Worksheet S–10 instructions and reporting through provider education and further refinement of the instructions as appropriate. We also encourage providers to share with their respective MAC any questions regarding clarifications of instructions, reporting, and submission deadlines.

We continue to believe that, as noted by a commenter, our efforts to refine the instructions and guidance have improved provider understanding of the Worksheet S–10 and added clarity to the instructions. We also recognize that there are continuing opportunities to further improve the accuracy and consistency of the information that is reported on the Worksheet S–10, and to the extent that commenters have raised new questions and concerns regarding the reporting requirements, we will attempt to address them through future rulemaking and/or sub-regulatory guidance and provider outreach. However, as stated in previous rules, we continue to believe that the Worksheet S–10 instructions are now sufficiently clear and allow hospitals to accurately complete Worksheet S–10s.

Regarding the commenters' request that CMS clarify whether non-Medicare bad debt is multiplied by CCR, we believe that the Worksheet S–10 instructions are clear and indicate that the CCR is multiplied by the non-Medicare bad debt amount on line 28.

Regarding the comments requesting specific structural changes to Worksheet S–10 and/or further clarification of the reporting instructions, we note that these comments fall outside the scope of this final rule. We note that a recent PRA package for hospital cost report is available at: *https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pralisting/cms-2552-10*.

We received comments regarding Worksheet S–10 data and audits.

Comment: In relation to the accuracy of the Worksheet S–10 data, one commenter urged CMS to refine the instructions for reporting of uncompensated care costs. The commenter's recommendations included that CMS should mitigate the effect of anomalies in the cost data for the COVID–19 PHE period and that CMS should consider the redistributive effects of the COVID–19 PHE for purposes of determining uncompensated care payments in future rulemaking. One commenter recommended that CMS work with impacted providers in upcoming years to ensure that the data from the COVID–19 PHE period is properly understood and correctly reported. Another commenter urged CMS to account for the unpredictability of the COVID–19 PHE, including the emergence of new variants, in determining uncompensated care payments for future years.

Response: In regard to requests for CMS to mitigate the effect of anomalies in FY 2020 through FY 2022 cost report data and account for the unpredictability of the COVID–19 PHE in determining uncompensated care payments for future years, we note that we are finalizing the proposal to use a three-year average of the most recently audited cost report data for FY 2024 and subsequent years. Using the three-year average will smooth the variation in year-to-year uncompensated care payments and lessen the impacts of COVID–19 PHE and future unforeseen events. We also note that the calculations for Factor 1 and Factor 2 reflect the estimated impact of the COVID–19 PHE on DSH payments. Further, we anticipate that there will be less fluctuation in cost report data as the PHE disruptions on healthcare utilization fade. We will continue to monitor the impacts of the PHE and will consider this issue further in future rulemaking, as appropriate.

Comment: Some commenters commended CMS for the agency's efforts to develop and improve the audit process for Worksheet S–10 data. Specifically, one commenter commended CMS for its efforts to audit all hospitals rather than only a portion, while another commenter recommended that CMS expend all the necessary resources to continue to audit Worksheet S–10 data for all DSH eligible hospitals.

Echoing concerns expressed in previous years, commenters encouraged CMS to work with MACs to make the audit process clearer, more consistent, and more complete. The same commenters provided several recommendations, including that CMS establish a standardized process across auditors, develop uniform standards regarding information submission and acceptable documentation to meet audit requirements, develop a transparent timeframe with sufficient lead time, target specific data aspects for the audit, and develop a process for timely appeals. Specifically, one commenter recommended that all hospitals be audited using the same protocols and that having only some hospitals subject to desk reviews is inequitable. A few commenters cited the Medicare wage index audit as a model that CMS could use for Worksheet S–10 audits. One commenter suggested that CMS ensure

that Worksheet S–10 audits impose minimal burden and are equitable and uniform across hospitals. The same commenter also suggested that CMS consider making the audit process more transparent by disclosing criteria used to identify hospitals for audits and publishing audit protocols in advance to allow hospitals time and opportunity to respond to audits and address findings. Other recommendations from this commenter included that CMS should conduct audits in advance of using data for payment rate setting such that data are accurate and final, select hospitals for audits in an equitable and systematic way, and review audit findings to ensure that MACs and subcontractors are consistently performing audits according to protocols.

Response: We thank commenters for their feedback on the audits of the FY 2019 Worksheet S–10 data and their recommendations for future audits. As we have stated previously in response to comments regarding audit protocols, these are provided to the MACs in advance of the audit so as to assure consistency and timeliness in the audit process. We began auditing the FY 2019 Worksheet S–10 data for selected hospitals last year so that the audited uncompensated care data for these hospitals would be available in time for use in the FY 2023 IPPS/LTCH PPS proposed rule. We chose to focus the audit on the FY 2019 cost reports in order to maximize the available audit resources. Similarly, as discussed in the FY 2022 IPPS/LTCH PPS final rule, we chose to focus the audits on the FY 2018 cost reports in order to maximize the available audit resources prior to the FY 2022 rulemaking. In response to the consistent feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we have also started the process of auditing FY 2020 Worksheet S–10 data.

We appreciate all commenters' input and recommendations on how to improve our audit process and reiterate our commitment to continue working with the MACs and providers on audit improvements, which include making changes to increase the efficiency of the audit process, building on the lessons learned in previous audit years. We will take these recommendations into consideration for future rulemaking. Regarding commenters' requests for a standard audit timeline, we do not intend to establish a fixed timeline for audits across MACs at this time such that we can retain the flexibility to use our limited audit resources to address and prioritize audit needs across all CMS programs each year. We note that MACs collaborate with providers regarding scheduling dates during the Worksheet S–10 audit process. We also note that MACs work closely with providers to balance the time needed to complete the Worksheet S–10 audits and to minimize the burden on providers and will continue to do so.

Regarding commenters' requests that we make public the audit instructions and criteria, as we previously stated in the FY 2022 IPPS/LTCH final rule and in prior rules, we do not make review protocols public as CMS desk review and audit protocols are confidential and are for CMS and MAC use only. We note that there is no requirement under either the Administrative Procedure Act or the Medicare statute that CMS establish audit protocols through notice and comment rulemaking. Rather, it is sufficient that we provide impacted parties with notice of our proposed methodology and the data sources that will be used, so that they may have a meaningful opportunity to submit their views on the proposed methodology and the adequacy of the data for the intended purpose. Similarly, there is no requirement that we provide an opportunity for comment on the actual findings or audit disallowances determined for each hospital as these results are confidential to each hospital.

Concerning commenters' recommendations that we establish a timely review and appeals process for the Worksheet S–10 audits, we do not plan to introduce such a process at this time in order to maximize limited audit resources. However, we will continue to work with impacted parties to address their concerns regarding the accuracy and consistency of data reported on Worksheet S–10. We will also continue to work to further improve reporting through revised instructions, and will also work with MACs to ensure a more consistent audit process across providers and MACs.

Regarding commenters' recommendations that we establish a similar process to that of the wage index audits, at this point we do not plan to introduce an audit process with such a structure in order to maximize limited audit resources.

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28392), for purposes of determining Factor 3 for FY 2023 and subsequent fiscal years, we are continuing to apply the following policies: (1) the merger policies that were initially adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021), as modified in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58828 and 58829) to incorporate the use of a multiplier to account for merger effective date; (2) the policy for hospitals with multiple cost reports, beginning in the same fiscal year, of using the longest cost report and annualizing uncompensated care data if a hospital's cost report does not equal 12 months of data; (3) the policy, as modified in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58829) and as further modified as proposed in the FY 2023 IPPS/LTCH PPS proposed rule, for the rare case where a hospital has a cost report that starts in one fiscal year and spans the entirety of the following fiscal year, such that the hospital has no cost report for that subsequent fiscal year, of using the cost report that spans both fiscal years for the latter fiscal year; (4) the new hospital policy, as modified in the FY 2020 IPPS/LTCH PPS final rule and as further modified as proposed in this section; (5) the newly merged hospital policy, with the modifications proposed in the FY 2023 IPPS/LTCH PPS proposed rule; and (6) the policies regarding the application of statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10, as modified as proposed in the FY 2023 IPPS/LTCH PPS proposed rule.

Because we proposed to use multiple years of cost reports to determine Factor 3 starting in FY 2023, we determined that it would also be necessary to make a further modification to the policy regarding cost reports that start in one fiscal year and span the entirety of the following fiscal year. Specifically, in the rare cases when we use a cost report that starts in one fiscal year and spans the entirety of the subsequent Federal fiscal year to determine uncompensated care costs for the subsequent Federal fiscal year, we would not use the same cost report to determine the hospital's uncompensated care costs for the earlier fiscal year. We explained that using the same cost report to determine uncompensated care costs for both fiscal years would not be consistent with our intent to smooth year-to-year variation in uncompensated care costs. As an alternative, we proposed to use the hospital's most recent prior cost report, if that cost report spans the applicable period. In other words, in determining Factor 3 for FY 2023, we would not use the same cost report to determine the hospital's uncompensated care costs for both FY 2018 and FY 2019. Rather, we would use the cost report that spans the entirety of FY 2019 to determine uncompensated care costs for FY 2019 and we would use the hospital's most recent prior cost report to determine its uncompensated care costs for FY 2018,

provided that cost report spans some portion of Federal fiscal year 2018.

We did not receive comments on this proposed modification. We are finalizing as proposed.

• *Scaling Factor*

To address the effects of the calculating Factor 3 using data from multiple fiscal years, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28392) we proposed to apply a scaling factor to the Factor 3 values calculated for all DSH eligible hospitals so that total uncompensated care payments to hospitals that are projected to be eligible for DSH for a fiscal year will be consistent with the estimated amount available to make uncompensated care payments for that fiscal year. Specifically, we proposed to adopt a policy under which we divide 1 (the expected sum of all DSH-eligible hospitals' Factor 3 values) by the actual sum of all DSH eligible hospitals' Factor 3 values and then multiply the quotient by the uncompensated care payment determined for each DSH eligible hospital to obtain a scaled uncompensated care payment amount for each hospital. This process is designed to ensure that the sum of the scaled uncompensated care payments for all hospitals that are projected to be DSH eligible is consistent with the estimate of the total amount available to make uncompensated care payments for the applicable fiscal year. In the proposed rule, we noted that a similar scaling factor methodology was previously used in both FY 2018 (82 FR 38214 and 38215) and FY 2019 (83 FR 41414), when the Factor 3 calculation also included multiple years of data.

We did not receive comments on this proposed scaling factor policy. We are finalizing as proposed.

• Modifications to New Hospital Policy for Purposes of Factor 3

We proposed to modify the new hospital policy that was initially adopted in the FY 2020 IPPS/LTCH PPS final rule to determine Factor 3 for new hospitals. Consistent with our proposal to use multiple years of cost reports to determine Factor 3, we proposed to define new hospitals as hospitals that do not have cost report data for the most recent year of data being used in the Factor 3 calculation. In other words, the cut-off date for the new hospital policy would be the beginning of the Federal fiscal year after the most recent year for which audits of the Worksheet S–10 data have been conducted. For FY 2023, the FY 2019 cost reports are the most recent year of cost reports for which audits of Worksheet S–10 data have been conducted. Thus, hospitals with CCNs established on or after October 1, 2019, would be subject to the new hospital policy in FY 2023.

Under the proposed modification to the new hospital policy, we would continue the policy established in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42370) that if a new hospital has a preliminary projection of being eligible for DSH payments based on its most recent available disproportionate patient percentage, it may receive interim empirically justified DSH payments. However, new hospitals would not receive interim uncompensated care payments during FY 2023 because we would have no FY 2018 or FY 2019 uncompensated care data on which to determine what those interim payments should be. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2023 cost report.

We also proposed to modify the methodology used to calculate Factor 3 for new hospitals. Specifically, we proposed to determine Factor 3 for new hospitals using a denominator based solely on uncompensated care costs from cost reports for the most recent fiscal year for which audits have been conducted. For example, if a new hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2023, the hospital will receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2023 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2019 cost reports for all DSH-eligible hospitals. In addition, we proposed to apply a scaling factor, as discussed previously, to the Factor 3 calculation for a new hospital. We explained that we believe applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, in order to improve consistency and predictability across all hospitals.

• Modifications to the Newly Merged Hospital Policy

In the FY 2023 IPPS/LTCH PPS rule, we stated that we will continue to treat hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule, for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year will be recalculated similar to new hospitals (79 FR 50021 and 50022). Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, we will continue to treat newly merged hospitals in a similar manner to new hospitals, such that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, the data from the newly merged hospital's cost report will be annualized for purposes of the Factor 3 calculation. Consistent with the proposed modification to the methodology used to determine Factor 3 for new hospitals described previously, we proposed to determine Factor 3 for newly merged hospitals using a denominator that is the sum of the uncompensated care costs for all DSH-eligible hospitals, as reported on Worksheet S–10 of their cost reports for the most recent fiscal year for which audits have been conducted. In addition, we would apply a scaling factor, as discussed previously, to the Factor 3 calculation for a newly merged hospital. We stated our belief that applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, in order to improve consistency and predictability across all hospitals.

We also explained that consistent with past policy, interim uncompensated care payments for the newly merged hospital will be based only on the data for the surviving hospital's CCN available at the time of the development of the final rule. In other words, for FY 2023, the eligibility of a newly merged hospital to receive interim uncompensated care payments and the amount of any interim uncompensated care payments, would be based on the uncompensated care costs from the FY 2018 and FY 2019 cost reports available for the surviving

CCN at the time the final rule is developed. However, at cost report settlement, we would determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2023 cost report. That is, we would revise the numerator of Factor 3 for the newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2023 cost report. The denominator would be the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2019 cost reports for all DSH-eligible hospitals, which is the most recent fiscal year for which audits have been conducted.

Comment: A couple of commenters expressed support for the policy currently in place for newly merged hospitals under which interim uncompensated care payments are based on the data for the surviving hospital's CCN available at the time of development of the final rule. These commenters also indicated support for continuing the policy in place for new hospitals, under which new hospitals with a CCN established on or after October 2019 with a preliminary projection of being eligible for DSH payments would receive interim empirically justified DSH payments. MACs would then make the final determination concerning whether a new hospital is eligible to receive DSH payments at cost report settlement based on the new hospital's FY 2023 cost report. One commenter requested that CMS provide clarification regarding which cost report would be used in the numerator of the Factor 3 calculation for a newly merged hospital or new hospital, and whether the cost report beginning or ending in FY 2023 would be used.

Response: We appreciate the support for our current policies for new and newly merged hospitals. In response to the comment asking for clarification on whether a newly merged hospital or new hospital would use its cost report beginning or ending in FY 2023, we note that the new hospital policy and the newly merged hospital policy are based on the start date of the hospital's cost reporting period. Specifically, the Factor 3 calculation for a new hospital will be based on the hospital's FY 2023 cost report (that is, a cost report with a start date on or after October 1, 2022, and on or before September 30, 2023). The numerator of the hospital's Factor 3 will be the hospital's total uncompensated care costs from the Worksheet S–10 Line 30 of its FY 2023 cost report (annualized, if necessary). The denominator will be the total national uncompensated care costs from the FY 2019 cost reports as calculated in this FY 2023 IPPS/LTCH PPS final rule. In the case of a new hospital or a newly merged hospital that has a cost report that spans multiple Federal fiscal years, if the cost report is a FY 2023 cost report, there is only one denominator in the Factor 3 calculation. In addition, the pro rata calculation (*i.e.,* the hospital's cost reporting period spans different Federal fiscal years) for a new hospital or a newly merged hospital is calculated using only the FY2023 total uncompensated care amount (that is, the Factor 3 is multiplied by the FY 2023 total uncompensated care amount, as finalized in this final rule.).

After consideration of the comments received, we are finalizing the proposed modifications to the new hospital and newly merged policies.

• CCR Trim Methodology

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). Consistent with the process for trimming CCRs used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831 and 58832), we explained in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28393) that we will apply the following steps to determine the applicable CCR for FY 2018 reports and FY 2019 reports separately:

Step 1: Remove Maryland hospitals. In addition, we will remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: Calculate a CCR ''ceiling'' for the applicable fiscal year with the following data: for each IPPS hospital that was not removed in Step 1 (including non-DSH eligible hospitals), we use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report will be selected.) The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for the applicable fiscal year for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for the applicable fiscal year greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling''). For purposes of both the proposed rule and this final rule, the statewide average CCR was applied to 8 hospitals' FY 2018 reports, of which 3 hospitals had FY 2018 Worksheet S–10 data. The statewide average CCR was applied to 14 hospitals' FY 2019 reports, of which 6 hospitals had FY 2019 Worksheet S–10 data.

Step 5: For hospitals that did not report a CCR on Worksheet S–10, Line 1, we assign them the statewide average CCR for the applicable fiscal year as determined in step 3.

After completing the previously described steps, we re-calculate the hospital's uncompensated care costs (Line 30) for the applicable fiscal year using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

We did not receive any comments on the discussion of CCR trim methodology. We are finalizing as proposed.

• Modifications to the Uncompensated Care Data Trim Methodology

After applying the CCR trim methodology, there are rare situations where a hospital has potentially aberrant uncompensated care data for a fiscal year that are unrelated to its CCR. Therefore, in the FY 2023 IPPS LTCH/PPS proposed rule, we explained that under the trim methodology for potentially aberrant UCC that was included as part of the methodology for purposes of determining Factor 3 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), if the hospital's uncompensated care costs for FY 2018 or FY 2019 are an extremely high ratio (greater than 50 percent) of its total operating costs in the applicable fiscal year, we will determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs for the applicable fiscal year. Specifically, if a hospital's FY 2018 cost report is determined to include potentially

aberrant data, data from its FY 2019 cost report will be used for the ratio calculation. Thus, the hospital's uncompensated care costs for FY 2018 will be trimmed by multiplying its FY 2018 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2019 cost report to calculate an estimate of the hospital's uncompensated care costs for FY 2018 for purposes of determining Factor 3 for FY 2023. Because we proposed to use multiple years of cost reports in the Factor 3 calculation for FY 2023, we would apply this same approach to address potentially aberrant data in the FY 2019 cost report, by trimming based on the hospital's FY 2020 cost report.

In the FY 2023 IPPS/LTCH PPS proposed rule, we noted that we have audited the FY 2018 and the FY 2019 Worksheet S–10 data for a number of hospitals. Because the UCC data for these hospitals have been subject to audit, we stated our belief that there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, consistent with the policy that was adopted in the FY 2021 IPPS/LTCH PPS final rule, we stated that it would be unnecessary to apply the trim methodology for a fiscal year for which a hospital's UCC data have been audited.

In addition to the UCC trim methodology, we stated that we would continue to apply a trim specific to certain hospitals that do not have audited FY 2018 Worksheet S–10 data and/or audited FY 2019 Worksheet S–10 data. We noted that in rare cases, hospitals that are not currently projected to be DSH eligible and that do not have audited Worksheet S–10 data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). Similar to the approach initially adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45245 and 45246), we proposed to continue to use a threshold of t3 standard deviations from the mean ratio of insured patients' charity care costs to total uncompensated care costs (line 23 column 2 divided by line 30) and a dollar threshold that is the median total uncompensated care cost reported on most recent audited cost reports for hospitals that were projected to be DSH-eligible. We stated that we continue to believe these thresholds are appropriate, in order to address potentially aberrant data. However, we proposed to modify the calculation to include Worksheet S–10 data from IHS/Tribal hospitals and Puerto Rico hospitals consistent with our proposal to begin using Worksheet S–10 data to determine Factor 3 for these hospitals. We also proposed to apply the same thresholds to identify potentially aberrant charity care costs data for all cost reporting years that are used in determining Factor 3. We noted that based on calculations from the FY 2019 reports, the threshold amounts were similar to FY 2018 reports; therefore, we explained that we believe it is reasonable to use the same thresholds to identify aberrant data for both years. Thus, under the proposal, in FY 2023 we would use the same thresholds to identify potentially aberrant data for both FY 2018 and FY 2019 reports. In addition, we proposed to apply the same threshold amounts originally calculated for the FY 2018 reports to identify potentially aberrant data for subsequent fiscal years in order to facilitate transparency and predictability. Therefore, for FY 2023 and subsequent fiscal years, we proposed that in the rare case that a hospital's insured patients' charity care costs are greater than $7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total uncompensated care costs (line 30) is greater than 60 percent, we would exclude the hospital from the prospective Factor 3 calculation. We explained that this trim would only impact hospitals that are not currently projected to be DSH-eligible; and therefore, are not part of the calculation of the denominator of Factor 3, which includes only uncompensated care costs for projected DSH-eligible hospitals. Consistent with the approach adopted in the FY 2022 IPPS/LTCH PPS final rule, if a hospital would be trimmed under both the UCC trim methodology and this alternative trim, we would apply this trim in place of the existing UCC trim methodology. We stated that we continue to believe this alternative trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the UCC trim methodology, because the UCC trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs.

In addition, we proposed to continue to apply the policy adopted in the FY 2022 IPPS/LTCH PPS final rule, for the hospitals that would be subject to this alternative trim and are ultimately determined to be DSH-eligible at cost report settlement. We explained that if a hospital subject to this trim is ultimately determined to be DSH-eligible at cost report settlement, its uncompensated care payment should be calculated only after the hospital's reporting of insured charity care costs on its FY 2023 Worksheet S–10 has been reviewed. Accordingly, the MAC would calculate a Factor 3 for the hospital only after reviewing the uncompensated care information reported on Worksheet S–10 of the hospital's FY 2023 cost report. Then we would calculate Factor 3 for a hospital subject to this alternative trim using the same methodology used to determine Factor 3 for new hospitals. Specifically, the numerator would reflect the uncompensated care costs reported on the hospital's FY 2023 cost report, while the denominator would reflect the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2019 cost reports of all DSH-eligible hospitals. In addition, consistent with our proposed approach for new hospitals, we would apply a scaling factor, as discussed previously, to the Factor 3 calculation for these hospitals. We stated that we believe applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, in order to improve consistency and predictability across all hospitals.

We did not receive any comments on the proposed modifications to the uncompensated care data trim methodology. We are finalizing as proposed.

- Summary of Methodology

In summary, under the policies we are finalizing in this FY 2023 IPPS/LTCH PPS final rule, for FY 2023, we will compute Factor 3 for each hospital using the following steps:

Step 1: Select the hospital's longest cost report from its Federal fiscal year (FY) 2018 cost reports and the longest cost report from its FY 2019 cost reports. (Alternatively, in the rare case when the hospital has no cost report for a particular year because the cost report for the previous Federal fiscal year spanned the more recent Federal fiscal year, the previous Federal fiscal year cost report will be used in this step. In the rare case, that using a previous Federal fiscal year cost report results in a period without a report, we will use the prior year report, if that cost report spanned the applicable period. (For example, if a hospital does not have a FY 2019 cost report because the hospital's FY 2018 cost report spanned the FY 2019 time period, then we will use the FY 2018 cost report that spanned the FY 2019 time period for this step. Using the same example, where the hospital's FY 2018 report is

used for the FY 2019 time period, then we will use the hospital's FY 2017 report if it spans some of the FY 2018 time period. In other words, we will not use the same cost report for both the FY 2019 and the FY 2018 time periods.) In general, we note that, for purposes of the Factor 3 methodology, references to a fiscal year cost report are to the cost report that spans the relevant Federal fiscal year period.

Step 2: Annualize the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if a cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

Step 4: Calculate Factor 3 for all DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2018 cost report data and FY 2019 cost report data (from Step 1, 2 or 3). New hospitals and other hospitals that are treated as if they are new hospitals for purposes of Factor 3 are excluded from this calculation.

Step 5: Average the Factor 3 values from Step 4; that is, add the Factor 3 values for FY 2018 and FY 2019 for each hospital, and divide that amount by the number of cost reporting periods with data to compute an average Factor 3 for the hospital. Multiply by a scaling factor.

For FY 2024 and subsequent fiscal years, these steps will be calculated using the most recent 3 years of audited cost reports. (For example, in FY 2024, the FY 2018, FY 2019, and FY 2020 reports would be used.)

In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to make a conforming change to the existing regulation at § 412.106(g)(1)(iii)(C)(*8*) and to add a new regulation at § 412.106(g)(1)(iii)(C)(*10*) to reflect our proposal to calculate Factor 3 based on the most recent two years of audited data on uncompensated care costs in FY 2023. We also proposed to add § 412.106(g)(1)(iii)(C)(*11*) to reflect our proposal to calculate Factor 3 for FY 2024 and subsequent fiscal years based on a 3-year average of the most recent available audited data on uncompensated care costs.

We did not receive any comments on these proposed changes to regulations. We are finalizing the proposed changes with only minor conforming changes for internal consistency.

(d) Per Discharge Amount of Interim Uncompensated Care Payments

Since FY 2014, we have made interim uncompensated care payments during the fiscal year on a per discharge basis. We have used a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the hospital's uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount for the applicable fiscal year, is divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine the uncompensated care payment per discharge for that fiscal year.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45247 and 45248), we modified this calculation for FY 2022 to be based on an average of FY 2018 and FY 2019 historical discharge data, rather than a 3-year average that included data from FY 2018, FY 2019, and FY 2020. We explained our belief that computing a 3-year average with the FY 2020 discharge data would underestimate discharges, due to the decrease in discharges during the COVID–19 pandemic. For the same reason, we proposed to modify this calculation for FY 2023 to be based on the average of FY 2018, FY 2019, and FY 2021 historical discharge data, rather than a 3-year average of the most recent 3 years of discharge data from FY 2019, FY 2020, and FY 2021. We stated that computing a 3-year average using the most recent 3 years would potentially underestimate the number of discharges for FY 2023, due to the effects of the COVID–19 pandemic in FY 2020, which was the first year of the COVID–19 pandemic. Therefore, we explained our belief that the proposed modification may result in a better estimate of the number of discharges during FY 2023, for purposes of the interim uncompensated care payment calculation. In addition, we noted that our proposal to include discharge data from FY 2021 to compute this 3-year average was consistent with the proposed use of FY 2021 Medicare claims in the IPPS ratesetting, as discussed in section I.F. of the preamble of the FY 2023 IPPS/LTCH PPS proposed rule. Under this proposal, the resulting 3-year average of the number of discharges would be used to calculate a per discharge payment amount that will be used to make interim uncompensated care payments to each projected DSH-eligible hospital during FY 2023. We also explained that the interim uncompensated care payments made to a hospital during the fiscal year will be reconciled following the end of the year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the FY 2023.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), we finalized a voluntary process through which a hospital may submit a request to its MAC for a lower per discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the Federal fiscal year and/or once during the Federal fiscal year. In conjunction with this request, the hospital must provide supporting documentation demonstrating that there would likely be a significant recoupment (for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000) at cost report settlement if the per discharge amount is not lowered. For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its per discharge uncompensated care payment amount. As another example, a hospital might request that its per discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

Under the policy we finalized in the FY 2021 IPPS/LTCH PPS final rule, the hospital's MAC would evaluate these requests and the supporting documentation before the beginning of the Federal fiscal year and/or with midyear requests when the historical average number of discharges is lower than the hospital's projected FY 2023 discharges. If following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that will be made is to lower the per discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. If the MAC determines it would be appropriate to reduce the interim Medicare uncompensated care payment per discharge amount, that updated amount will be used for purposes of the outlier payment calculation for the remainder of the Federal fiscal year. We refer readers to the Addendum to this final

rule for a more detailed discussion of the steps for determining the operating and capital Federal payment rate and the outlier payment calculation. No change would be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, any change to the per discharge uncompensated care payment amount will not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

Comment: A couple of commenters recommended that CMS use the traditional payment reconciliation process to calculate final payments for uncompensated care costs pursuant to section 1886(r)(2) of the Act. These commenters did not object to CMS using prospective estimates, derived from the best data available, to calculate interim payments for uncompensated care costs. However, the commenters stated that interim payments should be subject to later reconciliation based on estimates derived from actual data from the federal fiscal year. These same commenters also asserted that CMS has failed to provide a meaningful opportunity to review and comment on the more recent data used in developing the final rule before the agency publishes the final rule.

Response: Consistent with the position that we have taken in rulemaking for previous years, we continue to believe that applying our best estimates of the three factors used in the calculation of uncompensated care payments to determine payments prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; 81 FR 56949; 82 FR 38195; 84 FR 42373; 85 FR 58833 and 86 FR 45246). We continue to believe that, in affording the Secretary the discretion to estimate the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree with the commenters' suggestion that we should establish a process for reconciling our estimates of uncompensated care payments, which would be contrary to the notion of a prospective payment system. Furthermore, we note that this rulemaking has been conducted consistent with the requirements of the Administrative Procedure Act and Title XVIII of the Act. Under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2023 IPPS/LTCH PPS proposed rule included a detailed discussion of our proposed methodology for calculating Factor 3 and the data that would be used. We made public the best data available at the time of the proposed rule in order to allow hospitals to understand the anticipated impact of the proposed methodology and submit comments, and we have considered those comments in determining our final policies for FY 2023.

(e) Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with this final rule, we will publish on the CMS website a table listing Factor 3 for all hospitals that we estimate will receive empirically justified Medicare DSH payments in FY 2023 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving an uncompensated care payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. However, we note that a Factor 3 will not be published for new hospitals and hospitals that are subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible.

We also will publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. In the DSH uncompensated care supplemental data file, we list new hospitals and the 10 hospitals that would be subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible, with a N/A in the Factor 3 column.

Hospitals had 60 days from the date of public display of the FY 2023 IPPS/LTCH PPS proposed rule in the **Federal Register** to review the table and supplemental data file published on the CMS website in conjunction with the proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of Worksheet S–10 data during the report submission process (for example, report not reflecting audit results due to MAC mishandling or most recent report differs from previously accepted amended report due to MAC mishandling). We stated that comments raising issues or concerns that are specific to the information included in the table and supplemental data file could be submitted by email to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We indicated that we would address comments related to mergers and/or reporting upload discrepancies submitted to the CMS DSH inbox as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of this FY 2023 IPPS/LTCH PPS final rule. All other comments submitted in response to our proposed policies for determining uncompensated care payments for FY 2023 must have been submitted in one of the three ways found in the **ADDRESSES** section of the proposed rule before the close of the comment period in order to be assured consideration. In addition, we note that the CMS DSH inbox is not intended for Worksheet S–10 audit process related emails, which should be directed to the MACs.

For FY 2023, we again proposed that hospitals would have 15 business days from the date of public display of this FY 2023 IPPS/LTCH PPS final rule in the **Federal Register** to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. Any changes to Factor 3 would be posted on the CMS website and would be effective beginning October 1, 2022. We also explained that we continue to believe that hospitals have sufficient opportunity during the comment period for the proposed rule to provide information about recent and/or pending mergers and/or to report upload discrepancies. Hospitals do not enter into mergers without advanced planning. A hospital can inform CMS during the comment period for the proposed rule regarding any merger activity not reflected in supplemental file published in conjunction with the proposed rule. As discussed in the proposed rule, we expected to use data from the March 2022 HCRIS extract for the FY 2023 final rule, which contributed to our increased confidence that hospitals would have be able to comment on mergers and report any upload discrepancies during the comment period for the FY 2023 IPPS/LTCH PPS proposed rule. However, we noted that in the event that there were any remaining merger updates and/or upload discrepancies after the final rule, the 15 business days from the date of

public display of the FY 2023 IPPS/LTCH PPS final rule deadline should allow for the time necessary to prepare and make any corrections to Factor 3 calculations before the beginning of the Federal fiscal year.

We did not receive comments on the notification process for mergers or data upload issues. We are finalizing our proposal to afford hospitals 15 business days from the public display of this FY 2023 IPPS/LTCH PPS final rule to submit via email any updated information on mergers and/or to report upload discrepancies. We also note that the historical FY 2018 and FY 2019 cost reports are publicly available on a quarterly basis on the CMS website for analysis and additional review of cost report data, separate from the supplemental data file published with this final rule.

E. Supplemental Payment for Indian Health Service and Tribal Hospitals and Puerto Rico Hospitals for FY 2023 and Subsequent Fiscal Years

In the IPPS/LTCH PPS rulemaking for several previous fiscal years, Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico have commented about the unique challenges they face with respect to uncompensated care due to structural differences in health care delivery and financing in these areas compared to the rest of the country. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28396), we referred readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45242 and 45243) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58824 and 58825) for a discussion of these comments. We also explained that we appreciated the concerns raised and the input offered by commenters regarding the methodology for calculating uncompensated care payments for IHS/Tribal hospitals and the Puerto Rico hospitals. After taking into consideration stakeholders' longstanding concerns and their input on potential approaches to address these concerns, we proposed to establish a new permanent supplemental payment under the IPPS for IHS/Tribal hospitals and hospitals located in Puerto Rico. As discussed in greater detail in the proposed rule, we stated our belief that the proposed new supplemental payment would mitigate the anticipated impact on IHS/Tribal hospitals and hospitals located in Puerto Rico from our proposal to discontinue the use of low-income insured days as a proxy for their uncompensated care costs for purposes of determining Factor 3 of the uncompensated care payment methodology by providing for an additional payment to these hospitals that would be determined based upon the difference between the amount of the uncompensated care payment determined for the hospital using Worksheet S–10 data and an approximation of the amount the hospital would have received if we had continued to use low-income insured days as a proxy for uncompensated care.

As background, beginning in the FY 2018 IPPS/LTCH PPS final rule when we first included Worksheet S–10 data in the calculation of Factor 3, and continuing through the FY 2022 IPPS/LTCH PPS final rule, we relied on the authority under section 1886(r)(2)(C)(i) of the Act to use alternative data that is a better proxy for the costs of hospitals for treating the uninsured in order to determine Factor 3 for IHS/Tribal and Puerto Rico hospitals using low-income insured days as a proxy for uncompensated care costs. Since FY 2019, Factor 3 for these hospitals has been determined using FY 2013 Medicaid days and the most recent available data on SSI days. We believed this approach was appropriate as the FY 2013 Medicaid days data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In addition, because we continued to use low-income insured patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we continued to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as initially adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956). However, we recognized that our proposal, which we are finalizing in this final rule, to discontinue the use of low-income insured days as a proxy for uncompensated care costs would result in a significant financial disruption to the IHS/Tribal hospitals and hospitals located in Puerto Rico. We explained that, for the vast majority of these hospitals, the proposal to use uncompensated care data reported on Worksheet S–10 to determine Factor 3 of the uncompensated care payment methodology would be expected to result in an approximately 90 to 100 percent reduction in uncompensated care payments for FY 2023 compared to FY 2022. We referred readers to section I.H. of Appendix A of the proposed rule for a discussion of the anticipated impact of the proposal to use uncompensated care costs from Worksheet S–10 to determine uncompensated care payments for IHS/Tribal hospitals and Puerto Rico hospitals and the proposal to establish a new supplemental payment for these hospitals.

In consideration of the unique circumstances faced by the hospitals and the comments received from IHS/Tribal hospitals and Puerto Rico hospitals in response to prior rulemaking, raising concerns regarding financial stability in the event of a change in the data used to determine Factor 3, we proposed to use our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to establish a new permanent supplemental payment under the IPPS for IHS/Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023. Section 1886(d)(5)(I) of the Act authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. We have determined, after taking into consideration stakeholders' comments from prior rulemakings, that the supplemental payment is necessary so as not to cause undue long-term financial disruption to these hospitals as a result of our proposal to discontinue the use of low-income insured days as a proxy for uncompensated care in determining Factor 3 for IHS/Tribal hospitals and Puerto Rico hospitals beginning in FY 2023. In the proposed rule, we stated our belief that the proposed supplemental payment would help to mitigate the anticipated impact of the proposed changes to the uncompensated care payment methodology for these hospitals and therefore prevent undue long-term financial disruption for these providers.

We also stated that the proposed new supplemental payment would not change in any way the DSH payment methodology under section 1886(d)(5)(F) of the Act or the uncompensated care payment methodology under section 1886(r) of the Act. Therefore, the total uncompensated care payment amount would not be affected by this proposal to establish a supplemental payment for IHS/Tribal and hospitals located in Puerto Rico nor would there be any impact on the amount of the uncompensated care payment determined for each DSH-eligible hospital under § 412.106(g)(1) of the regulations.

We proposed that for IHS and Tribal hospitals and hospitals located in Puerto Rico for which Factor 3 of the uncompensated care payment methodology was determined using the low-income insured days proxy in FY

2022, we would calculate a supplemental payment as follows. We would use the hospital's FY 2022 uncompensated care payment as the starting point for this calculation. We explained that using the FY 2022 uncompensated care payment would be an appropriate starting point because FY 2022 is the most recent year for which we used low-income insured days data in the determination of uncompensated care payments for IHS/Tribal hospitals and Puerto Rico hospitals and the purpose of the proposed supplemental payment is to avoid undue long-term financial disruption to these hospitals as a result of our proposal to discontinue the use of low-income insured days as a proxy for uncompensated care beginning in FY 2023. The base year amount would be calculated as the hospital's FY 2022 uncompensated care payment adjusted by one plus the percent change in the total uncompensated care amount between the applicable year (for example, FY 2023 for purposes of this rulemaking) and FY 2022, where the total uncompensated care amount for a year is determined as the product of Factor 1 and Factor 2 for the applicable year. For example, if a hospital's FY 2022 uncompensated care payment was 1 million, and the percent change between FY 2023 and FY 2022 total uncompensated care payments was negative 9.1 percent, then the hospital's FY 2023 base year amount would be 1 million * (1+(−0.091)), which is 909,000. For the hospitals that were not projected to be DSH eligible in FY 2022, we proposed to use the uncompensated care payment that the hospital would receive, if the hospital were to be determined to be DSH eligible in FY 2022 at cost report settlement. For purposes of the proposed rule, the percent change between the proposed FY 2023 uncompensated care amount and final FY 2022 uncompensated care amount was projected to be negative 9.1 percent. (This negative 9.1 percent change was calculated based on the difference between the proposed FY 2023 uncompensated care amount of approximately $6.537 billion and the final FY 2022 uncompensated care amount of approximately $7.192 billion, divided by the final FY 2022 uncompensated care amount). Therefore, we proposed to calculate each hospital's base year amount for FY 2023 by multiplying its FY 2022 uncompensated care amount by 0.909 (1–0.091). We note that in order to determine the base year amount for a future fiscal year, the calculation would be the hospital's FY2022 uncompensated care amount multiplied by one plus the percent change in total uncompensated care payments between FY 2022 and the applicable fiscal year. The hospital's supplemental payment for a fiscal year would then be determined as the difference between the hospital's base year amount and its uncompensated care payment for the applicable fiscal year as determined under § 412.106(g). If the base year amount is equal to or lower than the hospital's uncompensated care payment for the current fiscal year, the hospital would not receive a supplemental payment because the hospital would not be experiencing financial disruption in that year as a result of the use of uncompensated care data from the Worksheet S–10 in determining Factor 3 of the uncompensated care payment methodology.

We proposed to align the eligibility and payment processes for the new supplemental payment with the processes used to make uncompensated care payments. Consistent with the process for determining eligibility to receive interim uncompensated care payments adopted in the FY 2014 IPPS/LTCH final rule, for the supplemental payment, we proposed to base eligibility to receive interim supplemental payments on a projection of DSH eligibility for the applicable fiscal year. In addition, consistent with the approach that is used to calculate interim uncompensated care payments on a per discharge basis, for the supplemental payment, we proposed to use an average of historical discharges to calculate a per discharge amount for interim supplemental payments. We referred readers to the FY 2014 IPPS/LTCH PPS final rule for additional background and discussion of uncompensated care payment processes (78 FR 50643 through 50647). Consistent with our proposal to use 3 years of historical discharges to determine interim uncompensated care payments for a fiscal year, we proposed that the amount of a hospital's supplemental payment calculated for a fiscal year would be divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine an estimated per discharge payment amount.

For FY 2023, we proposed to use FY 2018, FY 2019, and FY 2021 discharge data to determine a hospital's historical 3-year average of discharges, because we continued to believe the FY 2020 discharge data would underestimate discharges, due to the effects of the COVID–19 pandemic in FY 2020. In addition, consistent with the policy of including per-discharge uncompensated care payment amounts in the outlier calculation, which was initially adopted in the FY 2014 IPPS/LTCH PPS final rule, we proposed to use our authority under section 1886(d)(5)(I) of the Act to include the per-discharge supplemental payment in the outlier payment determination under section 1886(d)(5)(A) of the Act. We referred readers to the Addendum to the proposed rule for further discussion of the outlier payment calculation.

Consistent with the process used to reconcile interim uncompensated care payments, we proposed that the MAC would reconcile the interim supplemental payments at cost report settlement to ensure that the hospital receives the full amount of the supplemental payment that was determined prior to the start of the fiscal year. Consistent with the process used for cost reporting periods that span multiple Federal fiscal years, we proposed that a pro rata supplemental payment calculation may be made if the hospital's cost reporting period differs from the Federal fiscal year. Thus, the final supplemental payment amounts that would be included on a cost report spanning two Federal fiscal years would be the pro rata share of the supplemental payment associated with each Federal fiscal year. This pro rata share would be determined based on the proportion of the applicable Federal fiscal year that is included in that cost reporting period. We referred readers to the FY 2014 interim final rule for additional background and discussion of the processes for determining pro rata uncompensated care payments (78 FR 61191 through 61196).

We proposed that the MAC would make a final determination with respect to a hospital's eligibility to receive the supplemental payment for a fiscal year, in conjunction with its final determination of the hospital's eligibility for DSH payments and uncompensated care payments for that fiscal year. We noted that if a hospital is determined not to be DSH eligible for a fiscal year then the hospital would not be eligible to receive a supplemental payment for that fiscal year. In the proposed rule, we stated our belief that linking eligibility for the supplemental payment to eligibility for DSH payments and the uncompensated care payment is appropriate because a hospital that is not eligible to receive an uncompensated care payment for a fiscal year would not experience any financial disruption due to the discontinuation of the low-income insured days proxy and the use of

Worksheet S–10 data in determining Factor 3 for that fiscal year.

In addition, we proposed that IHS/Tribal hospitals and Puerto Rico hospitals that do not have a FY 2022 Factor 3 amount determined under § 412.106(g)(1)(iii)(C)(9) using the low-income insured days proxy or that are new hospitals that begin participating in the Medicare program on or after October 1, 2022, would not be eligible to receive the supplemental payment. We explained that these hospitals will not experience any reduction to their uncompensated care payments due to the proposed discontinuation of the low-income insured days proxy because they are not currently receiving uncompensated care payments determined using the proxy. We proposed to redesignate the existing provision at § 412.106(h) as § 412.106(i) and to add a new provision at § 412.106(h) to reflect the methodology for calculating the supplemental payment for FY 2023 and subsequent fiscal years.

We sought comments on our proposal to establish this new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals. As discussed in section IV.D.3. of this final rule, we also solicited comments on alternatives both to our proposal to use data on uncompensated care costs from the Worksheet S–10 to determine Factor 3 for IHS/Tribal hospitals and Puerto Rico hospitals and to the continued use of low-income insured days as a proxy for the uncompensated care costs of these hospitals. In addition, we sought comments on how to best measure and define the uncompensated care costs associated with these hospitals that might not otherwise be captured in Factor 3 calculations based on Worksheet S–10 data. Given the close interrelationship between our proposed changes to the methodology for determining Factor 3 of the uncompensated care payment methodology for IHS/Tribal hospitals and Puerto Rico hospitals and the proposed new supplemental payment for these hospitals, we discuss the comments received on both proposals in this section of this final rule.

Comment: The majority of commenters expressed appreciation for CMS' creativity in devising the proposed new supplemental payment to mitigate the anticipated financial impact from the discontinuation of low-income insured days as a proxy for uncompensated care costs for IHS and Tribal hospitals and hospitals located in Puerto Rico. Some commenters stated there are longstanding inequities in DSH and uncompensated care calculations for Puerto Rico hospitals due to the lack of an SSI benefit for residents of the U.S. territories. These commenters also suggested an alternative methodology for calculating the supplemental payment for hospitals in Puerto Rico.

Specifically, the commenters recommended that CMS calculate the supplemental payment for Puerto Rico hospitals using a base year amount determined from Medicaid days and an SSI days proxy of at least 40 percent but no less than 35 percent of Medicaid days, instead of the current 14 percent. Commenters further suggested that CMS determine a second empirical DSH eligibility threshold for hospitals in Puerto Rico based on the suggested SSI days proxy of 40 percent of Medicaid days, such that if the sum of the Medicaid fraction and the SSI days proxy exceeds 15 percent, then the hospital would be eligible to receive uncompensated care payments and the new supplemental payment. A commenter, in support of this alternative methodology, noted that, under the proposed supplemental payment methodology, Puerto Rico hospitals would receive an 11.06 percent reduction in Medicare DSH payments in FY 2023 as compared to FY 2022. The same commenter noted that the reduction in DSH payments could also reduce Medicare Advantage (MA) benchmarks for Puerto Rico in 2024 and, as a result, impact approximately 630,000 Medicare beneficiaries enrolled in MA plans, including 280,000 dual-eligible individuals.

Another commenter expressed support for the proposed discontinuation of low-income insured days as a proxy for uncompensated care costs for IHS and Tribal hospitals and hospitals located in Puerto Rico. However, this commenter recommended that CMS reduce the size of supplemental payments to hospitals in Puerto Rico to an empirically justified level. This commenter noted that the continued use of Medicaid days as a proxy for uncompensated care costs in Puerto Rico has resulted in a substantial increase in uncompensated care payments. Further, this commenter stated that maintaining the overall payments at the proposed levels through the supplemental payment would create high Medicare profit margins at Puerto Rico hospitals and distort the MA benchmarks, as it would increase FFS spending by more than 25 percent above what it would have been if Puerto Rico hospitals received uncompensated care payments based only on their reported uncompensated care costs. The commenter also opposed the disbursement of the supplemental payments as an add-on payment to the IPPS payment rates for hospitals in Puerto Rico and recommended that uncompensated care payments not be factored into MA benchmarks.

A few commenters expressed support for the proposed supplemental payment without suggesting enhancements to the policy. One of these commenters emphasized the importance of implementing the supplemental payment as a permanent policy.

A commenter opposed CMS' proposal to discontinue the calculation of uncompensated care costs using low income insured days for hospitals in Puerto Rico without a separate policy in place for receiving the supplemental payment. Instead, the commenter suggested that CMS use a phased approach such that the agency would continue to calculate uncompensated care costs for hospitals in Puerto Rico using low income insured days until a future rulemaking. The commenter further suggested that CMS eventually phase in payments calculated using Worksheet S–10 along with the supplemental payment.

Another commenter specifically opposed the exclusion of new hospitals in Puerto Rico from receiving the supplemental payment. The same commenter noted that because hospitals newly established after October 2013 did not have Medicaid days for the period before the Affordable Care Act was implemented, the uncompensated care costs for these hospitals are already calculated using Worksheet S–10 but with no supplemental payments. The commenter also noted that because hospitals established after October 2013 operate under the same conditions as hospitals established before October 2013, these hospitals should receive the proposed supplemental payments in a manner similar to those hospitals for which we proposed to transition to the use of Worksheet S–10 data to determine uncompensated care costs starting in FY 2023. Finally, this commenter requested that CMS consider calculating uncompensated care costs for an impacted Puerto Rico hospital (established after 2013) for the period from FY 2020 through FY 2022 using Medicaid days and not Worksheet S–10 data.

Response: We appreciate this input from commenters regarding the proposal to establish a new supplement payment for hospitals in Puerto Rico and IHS and Tribal hospitals and the concerns raised regarding the proposed changes to the data used to determine uncompensated care costs for these hospitals. We continue to recognize the unique financial circumstances and challenges

faced by Puerto Rico hospitals related to uncompensated care cost reporting on Worksheet S–10. With regard to the recommendation to calculate the supplemental payment using a base year amount determined using Medicaid days and an SSI days proxy of at least 40 percent, we note that since FY 2019, Factor 3 for hospitals in Puerto Rico has been determined using FY 2013 Medicaid days and the most recent available data on SSI days and because residents of Puerto Rico are not eligible for SSI benefits, we continued to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as initially adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956). We also note that we did not receive comments expressing concerns regarding this policy when it was finalized for FY 2019. However, for the reasons explained in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28391), we have determined that data on low income insured days is no longer a good proxy for the costs of hospitals in treating the uninsured and that we can no longer conclude that alternative data to the data on uncompensated care costs reported on the Worksheet S–10 are available for Puerto Rico hospitals that are a better proxy for the costs of these hospitals in treating the uninsured.

With respect to the comment recommending that we adopt a second eligibility threshold for empirically justified DSH payments based on the suggested SSI days proxy of 40 percent of Medicaid days, we note that in the FY 2023 IPPS/LTCH PPS proposed rule, we did not propose to adopt a proxy for Puerto Rico hospitals' SSI days for purposes of determining eligibility to receive DSH payments and calculating the empirically justified Medicare DSH payment. Therefore, we consider this comment to be outside the scope of the proposed rule. We note, however, that while section 1886(r)(2)(C)(i) of the Act allows for the use of alternative data as a proxy to determine the costs of subsection (d) hospitals for treating the uninsured for purposes of determining uncompensated care payments, section 1886(r)(1) of the Act requires the Secretary to pay an empirically justified DSH payment that is equal to 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Section 1886(d)(5)(F)(vi) of the Act, which prescribes the disproportionate patient percentage used to determine empirically justified Medicare DSH payments, specifically refers to the SSI days in the Medicare fraction and does not allow the use of alternative data. Accordingly, we disagree with the commenter's assertion that there is legal support for CMS to use a proxy for Puerto Rico hospitals' SSI days in the calculation of the empirically justified Medicare DSH payment.

Regarding the comment that hospitals in Puerto Rico hospitals will receive an 11.06 percent reduction in Medicare DSH payments in FY 2023 as compared to FY 2022, we note that, under the policies we are finalizing in this final rule, the combined amount of uncompensated care payments and supplemental payments for FY 2023 will be less than 11.06 percent below the amount of uncompensated care payments for FY 2022. We refer readers to the discussion of the impact of our final policies regarding Medicare uncompensated care payments and the new supplemental payment in Section I.H. of Appendix A of this final rule. In addition, we note that the base year amount used in calculating the supplemental payment will change over time relative to the total uncompensated care amount. Accordingly, for years in which there is an increase in the total uncompensated care total amount, the hospital's supplemental payment calculation would reflect a higher base year amount, and for the years in which there is a decrease in the total uncompensated care total amount, the hospital's supplemental payment calculation would reflect a lower base year amount.

With regard to the comment that the supplemental payment would impact the Medicare Advantage benchmarks, we believe the combined amount of empirically justified DSH payments, uncompensated care payments, and supplemental payments to IHS/Tribal hospitals and Puerto Rico hospitals will be comparable to the amount these hospitals would have received if CMS had continued to use the low-income days proxy to determine Factor 3 of the uncompensated care payment methodology. As a result, the new supplemental payments are expected to have no impact on MA benchmarks in Puerto Rico. Given that the MA capitation calculations are on a different timeline than the annual rulemaking for the IPPS (that is, calendar year rather than Federal fiscal year), the 2024 MA benchmarks would be the first time any effects would be reflected.

We disagree with the commenter who noted that there is no mechanism in place for receiving the supplemental payment. We refer readers to the FY 2014 IPPS/LTCH PPS proposed rule for additional background and discussion of uncompensated care payment processes (78 FR 50643 through 50647). As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to determine an estimated per discharge add-on payment amount based on the amount of a hospital's supplemental payment calculated for a fiscal year divided by the hospital's historical three-year average of discharges, computed using the most recently available data.

Regarding the concerns raised with respect to our proposal that hospitals in Puerto Rico established after October 2013 would be ineligible to receive the supplemental payment, we note that, as explained in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to establish the supplemental payment to mitigate any long-term financial disruption as a result of our proposal to discontinue the use of low-income insured days as a proxy for uncompensated care costs in determining Factor 3. Uncompensated care costs for Puerto Rico hospitals established after October 2013 are already determined using Worksheet S–10 data. As a result, these hospitals will not experience any reduction to their uncompensated care payments due to the proposed discontinuation of the low-income insured days proxy because they are not currently receiving uncompensated care payments determined using the proxy. Thus, we do not believe it is appropriate to modify the proposed eligibility criteria for the supplemental payment to include these hospitals at this time. However, we intend to monitor uncompensated care payments to these hospitals and may revisit this issue in future rulemaking.

Regarding the commenter that requested that CMS consider calculating the uncompensated care costs for FY 2020 through FY 2022 for a Puerto Rico hospital (established after 2013) using Medicaid days and not Worksheet S–10 data, we believe this comment is out of scope of this rulemaking. We note that the policy for new hospitals in Puerto Rico was initially adopted in the FY 2019 IPPS/LTCH PPS final rule, and we did not propose any modifications to this policy in the FY 2023 IPPS/LTCH PPS proposed rule.

Comment: Commenters expressed support for CMS' proposal to establish a new supplemental payment for IHS and Tribal hospitals to mitigate the anticipated impact of the agency's proposal to discontinue the use of low-income insured days as a proxy to calculate uncompensated care payments for these hospitals. Commenters requested that CMS confirm that the

supplemental payments would result in an equal or higher uncompensated care payment amount than in prior years. Commenters also opposed the exclusion of new IHS and Tribal hospitals from receiving the supplemental payment, with another commenter suggesting that CMS finalize the supplemental payment for existing IHS/Tribal hospitals as an interim measure while the agency devises an alternate approach that would be applicable to all IHS/Tribal hospitals. These commenters also urged CMS to provide an option for hospitals to opt out of the new supplemental payment methodology in the future years if they preferred payment in a manner similar to non-Tribal hospitals.

Response: We appreciate the input from commenters on our proposal to establish a new supplemental payment for IHS and Tribal hospitals. We continue to recognize the unique nature of these hospitals and the special circumstances they face.

Regarding commenters' request that CMS confirm that the proposed supplemental payment will result in an overall payment amount that is equal to or higher than the uncompensated care payments for prior years determined using the low-income days proxy, we note that the base year amount used to calculate a hospital's supplemental payment will change over time relative to changes in the total uncompensated care amount. For years in which there is an increase in the total uncompensated care total amount, the hospital's supplemental payment calculation would use a higher base year amount, and for the years in which there is a decrease in the total uncompensated care total amount, the hospital's supplemental payment calculation would use a lower base year amount.

Regarding the concerns raised by commenters with respect to our proposal to limit the new supplemental payment to existing IHS/Tribal hospitals that have a Factor 3 amount for FY 2022 determined using the low-income insured days proxy, we note that, as explained in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to establish the supplemental payment to mitigate any long-term financial disruption as a result of our proposal to discontinue the use of low-income insured days as a proxy for uncompensated care costs in determining Factor 3. However, new IHS/Tribal hospitals for which uncompensated care costs have not previously been determined using the low-income insured days proxy will not experience any reduction to their uncompensated care payments due to the proposed discontinuation of the proxy. Thus, we do not believe it is appropriate to extend the supplemental payment to include new IHS/Tribal hospitals at this time. However, we will monitor uncompensated care payments to these hospitals and may revisit this issue in future rulemaking.

In regard to an option for hospitals to opt out of the new supplemental payment methodology in the future years, we believe that no modification to our proposed methodology is necessary, because, under the proposed supplemental payment methodology, which we are finalizing in this final rule, an IHS/Tribal hospital or Puerto Rico hospital will receive the full uncompensated care payment determined using its Worksheet S–10 data. A hospital will only receive the supplemental payment if it increases the overall amount payable to the hospital, so there does not appear to be a clear reason for a hospital to opt out of the supplemental payment.

After consideration of the comments received, we are finalizing both our proposal to discontinue the use of the low-income insured days proxy and to rely solely on Worksheet S–10 data to calculate Factor 3 of the uncompensated care payment methodology for IHS/Tribal hospitals and Puerto Rico hospitals and our proposal to establish a new supplemental payment for Puerto Rico hospitals and IHS/Tribal hospitals, without modification. We are also finalizing the proposed provision at § 412.106(h) governing the new supplemental payment without modification.

The percent change between the final FY 2023 uncompensated care amount and final FY 2022 uncompensated care amount is negative 4.4 percent. (This negative 4.4 percent change is calculated based on the difference between the final FY 2023 uncompensated care amount of approximately $6.874 billion and the final FY 2022 uncompensated care amount of approximately $7.192 billion, divided by the final FY 2022 uncompensated care amount). Therefore, consistent with the methodology in § 412.106(h)(3)(i), we will calculate each hospital's base year amount for FY 2023 by multiplying its FY 2022 uncompensated care amount by 0.956 (1 − 0.044).

F. Medicare Disproportionate Share Hospital (DSH) Payments: Counting Days Associated With Section 1115 Demonstrations in the Medicaid Fraction (§ 412.106)

In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed revisions to the regulation relating to the treatment of section 1115 demonstration days for purposes of the DSH adjustment (87 FR 28398 through 28402). The agency received numerous, detailed comments on this proposal. We thank the commenters for their input on the proposal. Due to the number and nature of the comments that we received on our proposal, and after further consideration of the issue, we have determined not to move forward with the current proposal. We expect to revisit the treatment of section 1115 demonstration days for purposes of the DSH adjustment in future rulemaking, and we encourage interested parties to review any future proposal on this issue and to submit their comments at that time.

V. Other Decisions and Changes to the IPPS for Operating Costs

A. Changes in the Inpatient Hospital Update for FY 2023 (§ 412.64(d))

1. FY 2023 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2023, we stated in the proposed rule that we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2022. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we stated that we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2023 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase

(with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act.

- An adjustment based on changes in economy-wide multifactor productivity (MFP) (the productivity adjustment).

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

We note, in compliance with section 404 of the MMA, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45204), we replaced the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets beginning in FY 2022.

We proposed to base the FY 2023 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2021 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2021, which was estimated to be 3.1 percent. We also proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate, to determine the FY 2023 market basket update in the final rule.

Comment: Several commenters were concerned the proposed market basket update was not accurately reflecting hospital input inflation citing many examples including ongoing labor shortages, supply chain disruptions, prices for medical equipment, and the impact of Ukraine/Russia war. They urged CMS to adjust its market basket update methodology for FY 2023 to adjust for more recent data and to further adjust its estimate to appropriately capture significant inflationary trends that will further fuel rising hospital operating costs but may not yet be fully captured in IGI's updated market basket forecast in the second quarter of 2022. Commenters requested CMS recognize that hospital inflation will generally lag economy-wide inflation and that the expectations for sustained inflation should be recognized in the projection of the hospital market basket for FY 2023. Several commenters stated the proposed market basket update is a time-lagged estimate that uses historical data to forecast into the future. The commenters stated that when historical data is no longer a good predictor of future changes, the market basket becomes inadequate. A commenter stated that the end of calendar year 2021 into calendar year 2022 should not be considered a steady-state economic environment that is a continuance of past trends. A commenter encouraged CMS to err on the side of steadily increasing inflation into 2023 rather than any material deceleration assumption.

Other commenters urged CMS to rely on more recent forecasts to determine the FY 2023 update. A commenter noted CBO May 2022 baseline projections which had a market basket increase that is 1.1 percentage points higher than the proposed FY 2023 IPPS market basket percentage increase. Several commenters requested that CMS review other inflation data sources such as the Consumer Price Index (CPI) and the core Personal Consumption Expenditures deflator, and suggested that the market basket increase at least match or exceed these rates of increases.

Response: Section 1886(b)(3)(B)(iii) of the Act states the Secretary shall update IPPS payments based on a market basket percentage increase that reflects an index of appropriately weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in such inpatient hospital services. The 2018-based IPPS market basket is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, of the same mix of goods and services purchased by hospitals in the base period. The general inflation measures cited by the commenters would not reflect this same mix of goods and services.

We agree with the commenters that recent higher inflationary trends have impacted the outlook for price growth over the next several quarters. At the time of the FY 2023 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2021 forecast with historical data through third quarter 2021, IGI forecasted the 2018-based IPPS market basket update of 3.1 percent for FY 2023 reflecting forecasted compensation prices of 3.8 percent (by comparison, compensation price growth in the 2018-based IPPS market basket averaged 2.2 percent from 2012–2021). As stated previously, in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2023 IPPS market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy (including the more recent historical CPI growth, impacts of the Russia/Ukraine war, current expectations regarding changes to Federal Reserve interest rates, and tight labor markets). Based on IGI's second quarter 2022 forecast with historical data through first quarter 2022, we are projecting a FY 2023 IPPS market basket update of 4.1 percent (reflecting forecasted compensation price growth of 4.8 percent) and productivity adjustment of 0.3 percentage point. Therefore, as discussed further in this section and after consideration of the comments received, for FY 2023, the final applicable percentage increase for a hospital that submitted quality data and is a meaningful EHR user is 3.8 percent (4.1 percent less 0.3 percentage point), compared to the 2.7 percent that was proposed. We note that the final FY 2023 IPPS market basket growth rate of 4.1 percent would be the highest market basket update implemented in an IPPS final rule going back to FY 1998.

Comment: Several commenters suggested that CMS use alternative sources of data that they stated better reflect input price inflation to calculate the FY 2023 market basket update. A commenter stated that in absence of such data, CMS is urged to consider an alternative approach to better align the market basket updates with increases in the costs needed to care for Medicare beneficiaries. Several commenters encouraged CMS to implement a higher market basket update than proposed, reflecting alternative sources of cost data such as the Medicare cost reports. A commenter requested that CMS provide a market basket update of at least 5 percent.

Several commenters proposed that CMS apply a market basket increase of approximately 8 percent representing estimated trends in allowable Medicare costs per risk-adjusted discharge from the Medicare cost reports from FY 2019 to FY 2020. To support this method, commenters provided the language in the IPPS statute and stated that they believe that Medicare cost report data meets the statutory requirement as these data capture all allowable costs, including personnel costs and excluding non-operating costs that comprise routine, ancillary, and special care unit inpatient hospital services. The commenter stated that given that these data comprise all the costs—on a volume and risk-adjusted basis—necessary to deliver hospital care it represents ''appropriately weighted indicators of changes in wages and prices which are representative of the mix of good and services . . .'' necessary to provide inpatient hospital care to Medicare beneficiaries. Commenters stated their belief that Medicare cost report data are a more

accurate projection of the cost inflation anticipated by hospitals during FY 2023 than the forecast IGI data used in the proposed rule. The commenters further noted that changes in volume and intensity are accounted for in the market basket update when CMS rebases or revises it, which they stated is infrequent, typically occurring once every four years. They believe their proposed methodology of using Medicare cost report data would fully account for changes in volume and acuity annually, thus resulting in a more accurate proxy.

Another commenter analyzed Medicare cost report data and found that compensation costs increased by more than the IPPS market basket updates of 3.0 percent and 2.4 percent for FYs 2020 and 2021, respectively. The commenter recommended that CMS adjust the IGI compensation price indices and the overall inpatient price indices based on the percent change in compensation costs as derived from the Medicare cost reports.

A commenter recommended that CMS use its exceptions and adjustments authority to substitute Premier Inc. data for the IGI forecast to provide hospitals with an increased payment update in FY 2023 to accurately reflect labor costs. Additionally, the commenter recommended that CMS' Office of the Actuary reevaluate the data sources that it uses for calculating labor costs and consider adopting new or supplemental data sources in future rulemaking that more accurately reflect the cost of labor, such as more real time data from the hospital community. While the commenter stated that they were unable to forecast a market basket update for FY 2023, they noted the substantial impact a 10 percent increase in the labor components would have on the historical market basket for FY 2021, increasing the estimate by several percentage points under this hypothetical scenario.

Response: We believe the 2018-based IPPS market basket increase adequately reflects the average change in the price of goods and services hospitals purchase in order to provide IPPS medical services, and is technically appropriate to use as the market basket percentage increase in accordance with section 1886(b)(3)(B)(iii). As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45213), the IPPS market basket is a fixed-weight, Laspeyres-type index that measures price changes over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services. As such, the IPPS market basket increase would reflect the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage price growth or higher energy prices), but would inherently not reflect other factors that might increase the level of costs, such as the quantity of labor used or any shifts between contract and staff nurses (which would be reflected in the Medicare cost report data). We note that cost changes (that is, the product of price and quantities) would only be captured in the market basket weights when the index is rebased and the base year is updated to a more recent time period.

We disagree with the commenters that costs as reported on the Medicare cost report are suitable for determining the trend in compensation prices for the market basket update. Section 1886(b)(3)(B)(iii) of the Act states the Secretary shall estimate a market basket percentage increase based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services. While the current IPPS market basket percentage increase captures price changes associated with the goods and services hospitals purchase in providing care, the Medicare cost report data also reflects factors that are beyond those that impact wage or price growth. For instance, overall costs as reported by hospitals would also reflect changes in the mix of inputs used to provide services; since 2020, observed IPPS case-mix (and associated higher payments to hospitals) has increased faster than in prior years and would likely reflect the use of more skilled care needed to provide these services.

Regarding commenters' request that CMS consider other methods and data sources to calculate the final rule market basket update, we believe the 2018-based IPPS market basket continues to appropriately reflect IPPS cost structures and we believe the price proxies used (such as those from BLS that reflect wage and benefit price growth) are an appropriate representation of price changes for the inputs used by hospitals in providing services. We further note that we did not propose to use other methods or data sources to calculate the final market basket update for FY 2023. Consistent with our proposal, we have used more recent historical data and an updated forecast (that reflects a revised inflationary outlook) to calculate a final IPPS market basket percentage increase for FY 2023 of 4.1 percent, which is one percentage point higher than the proposed market basket percentage increase of 3.1 percent set forth in the FY 2023 IPPS/LTCH PPS proposed rule.

Comment: Several commenters also expressed concerns regarding the use of BLS' Employment Cost Index (ECI), which accounts for 53 percent of the market basket, stating it did not accurately reflect hospitals' compensation costs after the labor market changes triggered by the PHE. A commenter stated that this claim can be evidenced by comparing growth in labor costs from the Medicare cost report data to the ECI growth. The commenters also state that hospitals have faced a shortage of local labor as the PHE has progressed and have had to increasingly turn to contract labor, particularly for the nursing professions, which in turn has contributed to increased compensation costs. The commenters noted that CMS's proposed market basket update reflected a 3.8 percent increase in compensation, which they believe does not accurately reflect changes in current labor costs that they believe are not transitory.

Commenters noted that the ECI does not capture inflation in contract labor compensation while the hospital market basket does include contract labor costs when calculating the compensation cost weights and stated that including the contract labor costs along with other compensation costs assumes contract labor compensation growth will grow at the same rate as non-contract labor compensation. The commenters stated that this assumption is not supported by evidence citing published studies. Commenters also noted analysis by Premier Inc., which showed faster hourly labor rates than the ECI for FY 2021.

Response: As previously discussed, section 1886(b)(3)(B)(iii) of the Act states the Secretary shall estimate a market basket percentage increase based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services. The 2018-based IPPS market basket is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured. This type of IPPS market basket has been in place since the implementation of the IPPS as well as used for other CMS market baskets.

For the compensation cost weight in the 2018-based IPPS market basket (which includes salaried and contract

labor employees), we use the ECI for wages and salaries and benefits for all civilian hospital workers to proxy the price increases of labor for IPPS hospitals. The ECI (published by the BLS) measures the change in the hourly labor cost to employers, independent of the influence of employment shifts among occupations and industry categories. We note that the Medicare cost report data shows contract labor hours account for about 3 percent of total compensation hours (reflecting employed and contract labor staff) for IPPS hospitals in 2020. Data through 2021 are incomplete at this time. Therefore, while we acknowledge that the ECI measures only reflect price changes for employed staff, we believe that the ECI for hospital workers is accurately reflecting the price change associated with the labor used to provide hospital care (as employed workers' hours account for 97 percent of hospital compensation hours) and appropriately does not reflect other factors that might affect labor costs. Therefore, we believe it continues to be an appropriate measure to use in the IPPS market basket. We also note that based on IGI's second quarter 2022 forecast with historical data through first quarter 2022, compensation price growth (using the ECIs) for FY 2023 is now projected to be 4.8 percent, which is 1.0 percentage point higher than projected price growth at the time of the FY 2023 IPPS/LTCH PPS proposed rule (3.8 percent).

Comment: A commenter encouraged CMS to consider whether additional changes are needed regarding the rebasing and revising of the market basket, given data from 2018 was relied upon in the FY 2022 IPPS/LTCH PPS final rule to determine the appropriate mix of goods and services, which may have been impacted by COVID–19. For example, they stated that during the pandemic there has been increased use of personal protective equipment, yet this utilization would not be captured in the market basket, which was rebased and revised in the FY 2022 IPPS/LTCH PPS final rule.

Response: As described previously, the IPPS market basket measures price changes (including changes in the prices for wages and salaries) over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services until the market basket is rebased. The IPPS market basket was last rebased in the FY 2022 IPPS/LTCH PPS final rule using 2018 Medicare cost reports (86 FR 45194 through 45207), the most recent year of complete data available at the time of the rebasing. We note that we did not propose to rebase the IPPS market basket in the FY 2023 IPPS/LTCH PPS proposed rule. However, we did review more recent Medicare cost report data available for IPPS hospitals submitted as of March 2022, which includes data for 2019–2020. The Medicare cost report data (which does not allow us to separately identify costs for-PPE) showed slight decreases in the compensation cost weight in 2019 and 2020 resulting in a compensation cost weight that is roughly 1 percentage point less than the 2018-based IPPS market basket cost weight. Data through 2021 are incomplete at this time. The data also showed slight increases over the 2018 to 2020 time period in the pharmaceuticals cost weight and home office cost weight of about 0.3 percentage point each. Based on this preliminary analysis, the impact on the cost weights through 2020 are minimal and it is unclear whether these trends (particularly the compensation cost weight) through 2020 are reflective of sustained shifts in the cost structure for hospitals or whether they were temporary as a result of the PHE. Therefore, we continue to believe it is premature at this time to use more recent Medicare cost report data to derive a rebased and revised IPPS market basket. We will continue to monitor these data and any changes to the IPPS market basket will be proposed in future rulemaking.

Comment: Several commenters expressed concerns about the market basket update calculations. Commenters stated that CMS calculates the percent change by dividing the average input price indices in the most recent four quarters by the average input price index in the previous four quarters as derived from the most recently available IGI forecast. However, the commenter stated that CMS does not consider the difference between the base year estimates (from the time when prior year payment rates are finalized) and updated estimates of the base year indices since the prior year's market basket update calculation. Therefore, they stated this current update method does not account for substantial forecast errors driven by an unusually fast acceleration of the inflation rate such as occurred in FY 2021. They urge CMS to leverage its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to modify its methodology for FY 2023 to account for the substantial forecast error in FYs 2021 and 2022. A commenter added that it believes the understatement of the hospital market basket for FY 2021 and FY 2022 and potentially FY 2023 as well is such an occasion for using the exceptions and adjustments authority. The commenter stated that Premier data collected directly from hospitals is showing a 10 percent increase in 2022 to date for hospital compensation (67.6 percent of the market basket) compared to the 3.8 percent being forecasted by IGI. The commenter recommended CMS make a one-time only forecast error correction on the FY 2021 and FY 2022 market basket of a combined 1.9 percentage points for FY 2023 using the exceptions and adjustments authority. The commenter also recommended that CMS use its exceptions and adjustments authority to substitute Premier data for the IGI forecast to provide hospitals with an increased payment update in FY 2023 to accurately reflect labor costs.

A commenter urged CMS to consider a one-time adjustment to ensure that the FY 2023 rate increase is applied to a base rate that more accurately incorporates actual inflation during the pandemic. The commenter cited the unprecedented nature of the pandemic and its extraordinary impact on hospital costs alongside record inflation for the basis of this one-time adjustment.

Response: Section 1886(b)(3)(B) of the Act sets forth the update to the standardized amounts based on the applicable percentage increase. Although the statute does not include a forecast error adjustment, commenters requested that CMS use its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to modify its methodology to account for the forecast error in FYs 2021 and 2022. We note that we did not propose to use our authority under section 1886(d)(5)(I)(i) of the Act to apply a forecast correction in updating the IPPS rates for FY 2023. While there is no precedent to adjust for market basket forecast error in the IPPS operating payment update, the forecast error for a market basket update is equal to the actual market basket increase for a given year less the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. For example, the FY 2020 IPPS forecast error was −1.0 percentage point, and the FY 2021 IPPS forecast error was +0.7 percentage point; FY 2022 historical data are not yet available to calculate a forecast error for FY 2022. As we have discussed in past rulemaking, we believe that an important goal of a PPS is predictability. For these reasons, we do not believe it is appropriate to include adjustments to the market basket update for future years based on the difference between the actual and forecasted market basket increase in prior years. With regard to the comment

recommending the use of the Premier data, we refer to our response to this comment as previously discussed earlier in this section, regarding why we believe the 2018-based IPPS market basket increase adequately reflects the average change in the price of goods and services hospitals purchase in order to provide IPPS medical services, and is technically appropriate to use as the market basket percentage increase in accordance with section 1886(b)(3)(B)(iii).

We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing to use more recent data to determine the FY 2023 market basket update for the final rule. Specifically, based on more recent data available, we determined final applicable percentage increases to the standardized amount for FY 2023, as specified in the table that appears later in this section.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see *www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch*. In addition, we note that beginning with the FY 2022 IPPS/LTCH PPS final rule, we refer to this adjustment as the productivity adjustment rather than the MFP adjustment to more closely track the statutory language in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the adjustment continues to rely on the same underlying data and methodology.

For FY 2023, we proposed a productivity adjustment of 0.4 percent. Similar to the proposed market basket update, for the proposed rule, the estimate of the proposed FY 2023 productivity adjustment was based on IGI's fourth quarter 2021 forecast. As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2023 productivity adjustment for the final rule.

Comment: Several commenters requested that CMS use its ''special exceptions and adjustments'' authority under section 1886(d)(5)(I)(i) of the Act to eliminate the productivity adjustment for FY 2023. A commenter requested that CMS work with Congress to permanently eliminate the productivity adjustment to the annual hospital payment updates. Another commenter stated that, if CMS does not use more recent figures from BLS on economy-wide non-farm total factor productivity when determining the adjustment to the IPPS market basket update for FY 2023, then the highly unusual circumstances of the COVID–19 pandemic are sufficient reason for the Secretary to invoke section 1886(d)(5)(I)(i) ''exceptions and adjustments'' authority to provide a one-time adjustment that offsets application of the otherwise applicable productivity adjustment for FY 2023.

A commenter requested that CMS use its ''exceptions and adjustments'' authority under section 1886(d)(5)(I)(i) of the Act to remove the productivity adjustment for any fiscal year that was covered under PHE determination (for example, 2020, 2021, and 2022) from the calculation of market basket update for FY 2023 and any year thereafter.

A commenter recommended that CMS withhold the proposed −0.4 percent productivity adjustment until a federal fiscal year in which hospitals are not operating under the public health emergency (PHE).

Response: While we appreciate the commenters' concerns, section 1886(b)(3)(B)(xi)(I) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPPS market basket update when determining the applicable percentage increase. Section 1886(d)(5)(I)(i) of the Act authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate.

We further note that we did not propose to use our authority under section 1886(d)(5)(I)(i) of the Act in the FY 2023 IPPS/LTCH PPS proposed rule to offset the productivity adjustment for FY 2023. Based on the updated forecast for this final rule, and as discussed elsewhere, we are projecting a FY 2023 IPPS market basket update of 4.1 percent and a productivity adjustment of 0.3 percentage point for this final rule, as compared to the proposed market basket update of 3.1 percent and proposed productivity adjustment of 0.4 percentage point set forth in the proposed rule. Additionally, we note Congress has provided other funding to providers as a result of the COVID–19 PHE. Specifically, the CARES Act provided additional payments for cases of COVID–19 under the IPPS and also created the Provider Relief Fund to reimburse providers, including IPPS providers, for increased expenses or lost revenue attributable to COVID–19.

We thank the commenters for their comments. However, as previously noted, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, requires a productivity adjustment to the IPPS market basket update when determining the applicable percentage increase. Consistent with our proposal, we are using more recent data to determine the FY 2023 productivity adjustment for the final rule. Specifically, based on IGI's second quarter 2022 forecast, we are projecting a FY 2023 IPPS market basket update of 4.1 percent and productivity adjustment of 0.3 percentage point. Therefore, as discussed further in this section and after consideration of the comments received, for FY 2023, the final IPPS applicable percentage increase for a hospital that submitted quality data and is a meaningful EHR user is 3.8 percent (4.1 percent less 0.3 percentage point).

Comment: Several commenters expressed concerns about the productivity adjustment. A commenter stated that the measure of productivity used by CMS is intended to ensure payments more accurately reflect the true cost of providing patient care and effectively assumes the hospital field can mirror productivity gains across the

private nonfarm business sector. Several commenters stated that this has not been their experience during the pandemic. Commenters also stated that even before the pandemic, CMS Office of the Actuary questioned the wisdom of the underlying assumption in their analysis that compares private non-farm total factor productivity growth measure and a hospital-specific measure (*https://www.cms.gov/files/document/productivity-memo.pdf*). Commenters also stated that the latest data indicates a decrease in productivity, not gains, citing the latest BLS release of labor productivity data. Commenters had strong concerns about the proposed productivity adjustment given the extreme and uncertain circumstances in which their hospitals and health systems are currently operating. Several commenters requested CMS use the latest BLS data when determining the productivity adjustment for FY 2023.

Response: Section 1886(b)(3)(B)(xi)(II) of the Act requires the productivity adjustment be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business total factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). For the FY 2023 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2021 forecast, the productivity adjustment was projected to be 0.4 percentage point for FY 2023. For this final rule, based on IGI's second quarter 2022 forecast, we are updating the productivity adjustment to reflect more recent historical data as published by BLS as well as a revised economic outlook for FY 2022 and FY 2023. Using this more recent forecast, the FY 2023 productivity adjustment based on the 10-year moving average growth in economy-wide total factor productivity for the period ending FY 2023 is currently estimated to be 0.3 percent.

We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing as proposed to use more recent data to determine the FY 2023 productivity adjustment for the final rule.

Based on more recent data available for this FY 2023 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2022 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through the first quarter of 2022), we estimate that the FY 2023 market basket update used to determine the applicable percentage increase for the IPPS is 4.1 percent. Based on more recent data available for this FY 2023 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2022 forecast of the productivity adjustment), the current estimate of the productivity adjustment for FY 2023 is 0.3 percentage point.

As previously discussed, based on the more recent data available, for this final rule, we have determined four final applicable percentage increases to the standardized amount for FY 2023. For FY 2023, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount, as specified in this table.

FY 2023 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2023	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	4.1	4.1	4.1	4.1
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-1.025	-1.025
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-3.075	0	-3.075
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.3	-0.3	-0.3	-0.3
Applicable Percentage Increase Applied to Standardized Amount	**3.8**	**0.725**	**2.775**	**-0.3**

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less a productivity adjustment. (As previously noted, section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act.

Under current law, the MDH program is effective for discharges on or before September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430). Therefore, under current law, the MDH program will expire at the end of FY 2022. We

refer readers to section V.D. of the preamble of this final rule for further discussion of the expiration of the MDH program.

For FY 2023, we proposed the following updates to the hospital-specific rates applicable to SCHs: a proposed update of 2.7 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 0.375 percent for a hospital that submits quality data and is not a meaningful EHR user; a proposed update of 1.925 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and a proposed update of −0.4 percent for a hospital that fails to submit quality data and is not an meaningful EHR user. We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket update and the productivity adjustment), we would use such data, if appropriate, to determine the update in the final rule.

We did not receive any public comments on our proposed updates to hospital-specific rates applicable to SCHs. The general comments we received on the proposed FY 2023 update (including the proposed market basket update and productivity adjustment) are discussed earlier in this section. For FY 2023, we are finalizing the proposal to determine the update to the hospital specific rates for SCHs in this final rule using the more recent available data, as previously discussed.

For this final rule, based on more recent available data, we are finalizing the following updates to the hospital specific rates applicable to SCHs: An update of 3.8 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 0.725 percent for a hospital that submits quality data and is not a meaningful EHR user; an update of 2.775 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and an update of −0.3 percent for a hospital that fails to submit quality data and is not a meaningful EHR user.

2. FY 2023 Puerto Rico Hospital Update

Section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

For FY 2023, consistent with section 1886(b)(3)(B) of the Act, as amended by section 602 of Public Law 114–113, we are setting the applicable percentage increase for Puerto Rico hospitals by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS for Puerto Rico hospitals will be equal to the rate of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a 66⅔ percent reduction to three-fourths of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for Puerto Rico hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to the productivity adjustment at section 1886(b)(3)(B)(xi) of the Act. As noted previously, section 1886(b)(3)(B)(xi) of the Act states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

Based on IGI's fourth quarter 2021 forecast of the 2018-based IPPS market basket update with historical data through third quarter 2021, in the FY 2023 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we proposed a market basket update of 3.1 percent and a productivity adjustment of 0.4 percent. Therefore, for FY 2023, depending on whether a Puerto Rico hospital is a meaningful EHR user, we stated there would be two possible proposed applicable percentage increases that could be applied to the standardized amount. Based on these data, we determined the following proposed applicable percentage increases to the standardized amount for FY 2023 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we proposed an applicable percentage increase to the FY 2023 operating standardized amount of 2.7 percent (that is, the FY 2023 estimate of the proposed market basket rate-of-increase of 3.1 percent less an adjustment of 0.4 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we proposed an applicable percentage increase to the operating standardized amount of 1.15 percent (that is, the FY 2023 estimate of the proposed market basket rate-of-increase of 3.1 percent, less an adjustment of 1.55 percentage point (the proposed market basket rate-of-increase of 3.1 percent × 0.75 × (⅔) for failure to be a meaningful EHR user), and less an adjustment of 0.4 percentage point for the proposed productivity adjustment).

We did not receive any public comments on our proposed updates to the standardized amount for FY 2023 for Puerto Rico hospitals. The general comments we received on the proposed FY 2023 update (including the proposed market basket update and productivity adjustment) are discussed in greater detail earlier in this section. For FY 2023, we are finalizing the proposal to determine the update to the standardized amount for FY 2023 for Puerto Rico hospitals in this final rule using the more recent available data, as previously discussed.

As previously discussed in section V.A.1, based on more recent data available for this final rule (that is, IGI's second quarter 2022 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through the first quarter of 2022), we estimate that the FY 2023 market basket update used to determine the applicable percentage increase for the IPPS is 4.1 percent and the productivity adjustment is 0.3 percent. For FY 2023, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two

possible applicable percentage increases that can be applied to the standardized amount. Based on these data, accordance with section 1886(b)(3)(B) of the Act, we determined the following applicable percentage increases to the standardized amount for FY 2023 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, an applicable percentage increase to the FY 2023 operating standardized amount of 3.8 percent (that is, the FY 2023 estimate of the market basket rate-of-increase of 4.1 percent less an adjustment of 0.3 percentage point for the productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, an applicable percentage increase to the operating standardized amount of 1.75 percent (that is, the FY 2023 estimate of the market basket rate-of-increase of 4.1 percent, less an adjustment of 2.05 percentage point (the market basket rate-of-increase of 4.1 percent × 0.75 × (⅔) for failure to be a meaningful EHR user), and less an adjustment of 0.3 percentage point for the productivity adjustment).

FY 2023 APPLICABLE PERCENTAGE INCREASES FOR PUERTO RICO HOSPITALS PAID UNDER THE IPPS

FY 2023	Hospital is a Meaningful EHR User	Hospital is not a Meaningful EHR User
Market Basket Rate-of-Increase	4.1	4.1
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.05
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.3	-0.3
Applicable Percentage Increase Applied to Standardized Amount	**3.8**	**1.75**

B. Rural Referral Centers (RRCs) Annual Updates to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997, IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (5) and the September 30, 1988, **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

In the FY 2022 final rule (86 FR 45217), in light of the COVID–19 PHE, we amended the regulations at § 412.96(h)(1) to provide for the use of the best available data rather than the latest available data in calculating the national and regional CMI criteria. We also amended the regulations at § 412.96(c)(1) to indicate that the individual hospital's CMI value for discharges during the same Federal fiscal year used to compute the national and regional CMI values is used for purposes of determining whether a hospital qualifies for RRC classification. We also amended the regulations § 412.96(i)(1) and (2), which describe the methodology for calculating the number of discharges criteria, to provide for the use of the best available data rather than the latest available or most recent data when calculating the regional discharges for RRC classification.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and

regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The national median CMI value for FY 2023 is based on the CMI values of all urban hospitals nationwide, and the regional median CMI values for FY 2023 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). For the proposed rule, these values were based on discharges occurring during FY 2021 (October 1, 2020 through September 30, 2021), and include bills posted to CMS' records through December 2021. We believe that this is the best available data for use in calculating the national and regional median CMI values and is consistent with our finalized proposal to use the FY 2021 MedPAR claims data for FY 2023 ratesetting. We refer the reader to section I.F. of the preamble of this final rule for a complete discussion regarding our proposal and finalized policy to use the latest available data (that is, the FY 2021 MedPAR data) as the best available data for purposes of this FY 2023 rulemaking.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28404), we proposed that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2022, they must have a CMI value for FY 2021 that is at least—

- 1.8251 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region were set forth in a table in the proposed rule (87 FR 28405). We stated in the proposed rule that we intended to update the proposed CMI values in the FY 2023 final rule to reflect the updated FY 2021 MedPAR file, which will contain data from additional bills received through March 2022.

Comment: Commenters supported our proposal to use FY 2021 data to calculate the national and regional median CMI values for FY 2023.

Response: We appreciate the commenters' support.

Therefore, based on the best available data (FY 2021 bills received through March 2022), in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2022, they must have a CMI value for FY 2021 that is at least:

- 1.8262 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The final CMI values by region are set forth in the following table.

Region	Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.4961
2. Middle Atlantic (PA, NJ, NY)	1.59995
3. East North Central (IL, IN, MI, OH, WI)	1.7062
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7709
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.68745
6. East South Central (AL, KY, MS, TN)	1.6754
7. West South Central (AR, LA, OK, TX)	1.8756
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.896
9. Pacific (AK, CA, HI, OR, WA)	1.8547

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

3. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28406), for FY 2023, we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2020 (that is, October 1, 2019 through September 30, 2020). We believe that this is the best available data for use in calculating the median number of discharges by region and is consistent with our finalized data proposal to use cost report data from cost reporting periods beginning during FY 2020 for FY 2023 ratesetting. We refer the reader to section I.F. of the preamble of this final rule for a complete discussion regarding our proposal and finalized policy to use the latest available data (that is, cost reports beginning during FY 2020) as the best available data for purposes of this FY 2023 rulemaking.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28405), we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2022, must have, as the number of discharges for its cost reporting period that began during FY 2020, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2023 IPPS/LTCH PPS proposed rule at 87 FR 28406). In the

proposed rule, we stated that we intended to update to update these numbers in the FY 2023 final rule based on the latest available cost report data.

Comment: Commenters supported our proposal to use FY 2020 data to calculate median number of discharges by region for FY 2023.

Response: We appreciate the commenters' support.

Therefore, based on the best available discharge data at this time, that is, for cost reporting periods that began during FY 2020, the final median number of discharges for urban hospitals by census region are set forth in the following table.

Region	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,713
2. Middle Atlantic (PA, NJ, NY)	9,149
3. East North Central (IL, IN, MI, OH, WI)	7,635
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,298
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	9,833
6. East South Central (AL, KY, MS, TN)	9,206
7. West South Central (AR, LA, OK, TX)	5,747
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	7,693
9. Pacific (AK, CA, HI, OR, WA)	8,087

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this final rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

C. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Expiration of Temporary Changes to Low-Volume Hospital Payment Policy

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399), section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12) of the Act for FYs 2019 through 2022. Beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011, and the preexisting low-volume hospital payment adjustment methodology and qualifying criteria, as implemented in FY 2005 and discussed later in this section of this final rule, will resume. (For additional information on the temporary changes to the low-volume hospital payment policy, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41401). We also note, in that same final rule, we amended the regulations at 42 CFR 412.101 to reflect the provisions of section 50204 of the Bipartisan Budget Act of 2018.) We discuss the payment policies for FY 2023 in section V.C.3. of the preamble of this final rule.

2. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act. Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45219 through 45221), section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. Specifically, the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act were amended to specify that, for FYs 2019 through 2022, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Section 1886(d)(12)(D) of the Act was also amended to provide that, for discharges occurring in FYs 2019 through 2022, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

Beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011. Section 1886(d)(12)(C)(i) of the Act defines a low-volume hospital, for FYs 2005 through 2010 and FY 2023 and subsequent years, as a subsection (d) hospital that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year. Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term ''discharge'' means an inpatient acute care discharge of an individual, regardless of whether the individual is entitled to benefits under Medicare Part A (except with respect to FYs 2011 through 2018). Therefore, for FYs 2005 through 2010 and FY 2019 and subsequent years, the term ''discharge'' refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges), and as such the

term discharge continues to refer to total discharges for FY 2023 and subsequent years. Furthermore, section 1886(d)(12)(B) of the Act requires, for discharges occurring in FYs 2005 through 2010 and FY 2023 and subsequent years, that the Secretary determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges. The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.

Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. In the FY 2006 IPPS final rule (70 FR 47432 through 47434), we stated that multivariate analyses supported the existing low-volume adjustment implemented in FY 2005. Accordingly, under the existing regulations, in order for a hospital to continue to qualify as a low-volume hospital on or after October 1, 2022, it must have fewer than 200 total discharges during the fiscal year and be located more than 25 road miles from the nearest ''subsection (d)'' hospital (see § 412.101(b)(2)(i)). (For additional information on the low-volume hospital payment adjustment prior to FY 2018, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56941 through 56943). For additional information on the low-volume hospital payment adjustment for FY 2018, we refer readers to the FY 2018 IPPS notice (CMS–1677–N) that appeared in the April 26, 2018, **Federal Register** (83 FR 18301 through 18308). For additional information on the low-volume hospital payment adjustment for FY 2019 through FY 2022, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399).)

3. Payment Adjustment for FY 2023 and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, beginning with FY 2023, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and subsequent legislation. Therefore, effective for FY 2023 and subsequent years, under current policy at § 412.101(b), in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. For FY 2023 and subsequent years, the statute specifies that a low-volume hospital must have less than 800 discharges during the fiscal year. However, as required by section 1886(d)(12)(B)(i) of the Act and as discussed earlier, the Secretary has developed an empirically justifiable payment adjustment based on the relationship, for IPPS hospitals with less than 800 discharges, between the additional incremental costs (if any) that are associated with a particular number of discharges. Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief for low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. (Under the policy we established in that same final rule, hospitals with between 200 and 799 discharges do not receive a low-volume hospital adjustment.)

For FYs 2005 through 2010 and FY 2018 and subsequent years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011 through 2018, we used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years.

In addition to the discharge criterion, a hospital must also meet the mileage criterion to qualify for the low-volume payment adjustment. As specified by section 1886(d)(12)(C)(i) of the Act, a low-volume hospital must be more than 25 road miles (or 15 road miles for FYs 2011 through 2022) from another subsection (d) hospital. Accordingly, for FY 2023 and for subsequent fiscal years, in addition to the discharge criterion, the eligibility for the low-volume payment adjustment is also dependent upon the hospital meeting the mileage criterion at § 412.101(b)(2)(i), which specifies that a hospital must be located more than 25 road miles from the nearest subsection (d) hospital, consistent with section 1886(d)(12)(C)(i) of the Act. We define, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).

Comment: Several commenters opposed the change to the low-volume hospital policy in FY 2023. Many of those commenters stated that they are concerned about the financial impact resulting from the decrease in payments due to the expiration of the temporary changes to the low-volume hospital payment policy. Some commenters requested that CMS use its authority to extend the use of the modified definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals. Some commenters stated their belief that CMS has the authority to not allow the temporary changes to expire. A commenter requested CMS use its discretion under the Emergency Pandemic Declarations to extend the low-volume hospital payment policy.

Response: We appreciate the commenters' sharing their concerns regarding the financial impact resulting from the expiration of the temporary changes to the low-volume hospital payment policy. As previously discussed, section 1886(d)(12) of the Act sets forth the applicable low-volume hospital policy beginning FY 2023. In response to the comment that requested the temporary changes to the low-volume hospital policy be extended using the discretion under the Emergency Pandemic Declarations, we believe the commenter is referring to the use of waivers under Section 1135 of the Act. While this provision authorizes certain Medicare (and other) program requirements and conditions of participation to be waived during certain emergencies, this authority cannot be used to waive provisions of payment.

Comment: Several commenters support legislative action through the

Rural Hospital Support Act (H.R. 1887/S. 4009) to extend or make permanent the modifications to the low-volume hospital payment policy enacted by section 50204 of the Bipartisan Budget Act of 2018. Many commenters urged CMS to collaborate with Congress to extend or make permanent the modifications to the low-volume hospital payment policy. Other commenters stated that it is not the intent of Congress for the low-volume hospital payment policy to revert back to the historical statutory requirements. Some of these commenters believe that CMS is ignoring the congressional intent of this policy and denying a group of IPPS providers low-volume hospital payments with the reversion to the policy that was originally established for FY 2005. These commenters requested expanding eligibility for the discharge criteria to match the statutory requirement to include IPPS providers with 200–799 discharges. These commenters did not provide any data analysis in support of their comments to expand the low-volume hospital adjustment to qualifying hospitals that have more than 200 and less than 800 total discharges. A commenter requested that CMS update its regression analysis. The commenter stated that empirical justification used by CMS to determine the discharge criteria of less than 200 discharges is dated and that no rationale to support the ongoing validity of the previous analysis was provided in the proposed rule. The commenter also noted that even if the low-volume hospital discharge criteria were expanded to less than 800 total discharges, there would still only be a small number of hospitals to qualify for low-volume payment adjustment.

Response: We appreciate the commenters sharing their support for legislative action. We disagree that is contrary to the congressional intent for the low-volume hospital policy to revert back to the policy established under the original historical statutory requirements. As noted earlier in the preamble of this final rule and as discussed in response to public comments in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53408 through 53409), the FY 2014 IPPS/LTCH PPS final rule (78 50612 through 50613), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38184 through 38189) to implement the original low-volume hospital payment adjustment provision, and as mandated by statute, we developed an empirically justified adjustment based on the relationship between costs and total discharges of hospitals with less than 800 total (Medicare and non-Medicare) discharges. Specifically, we performed several regression analyses to evaluate the relationship between hospitals' costs per case and discharges, and found that an adjustment for hospitals with less than 200 total discharges is most consistent with the statutory requirement to provide for additional payments to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with lower numbers of discharges (69 FR 49101 through 49102). Based on these analyses, we established a low-volume hospital policy under which qualifying hospitals with less than 200 total discharges receive a payment adjustment of an additional 25 percent. (Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.) In the future, we may reevaluate the low-volume hospital adjustment policy; that is, the definition of a low-volume hospital and the payment adjustment. However, we are not aware of any analysis or empirical evidence that would support expanding the originally established low-volume hospital adjustment policy and we did not make any proposals regarding the low-volume hospital payment adjustment for FY 2023. For these reasons, we are not making any changes to the low-volume hospital payment adjustment policy in this final rule.

Comment: Some commenters urged CMS to expedite any changes to the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals, should Congress extend the current policy. They requested that low-volume hospital payments be restored quickly so that impacted providers are able to continue to provide quality care.

Response: We appreciate the commenters' request and, as in the past, we will make every effort to implement any extension of the low-volume payment policy as expeditiously as possible.

Comment: A commenter questioned how a hospital would qualify for low-volume payments while also adhering to the inpatient hospitals Conditions of Participation (CoP) since only hospitals with less than 200 total discharges would be eligible for the low-volume hospital adjustment beginning in FY 2023. The commenter argues that IPPS hospitals cannot adhere to the average daily census (ADC) and average length of stay (ALOS) thresholds in the discussion of the factors for state agencies to consider when certifying a facility as an inpatient hospital in the State Operations Manual (SOM).[214] Specifically, the commenter cites ''the ALOS of two midnights'' benchmark and the expectation ''to maintain an average daily census (ADC) of two patients.''

Response: While we appreciate the commenter's concern regarding compliance with the COPs and hospitals' certification as an inpatient hospital, it is not clear to us why a low-volume hospital payment adjustment criterion of less than 200 discharges would prevent a hospital from meeting ''the ADC and ALOS thresholds required for maintaining its certification and status as an inpatient facility.'' The low-volume payment adjustment provides an additional payment to hospitals that meet the low-volume hospital qualifying criteria and does not directly impact a hospital's ADC or ALOS. We also note that CMS considers multiple factors when determining certification for inpatient hospitals. ADC and ALOS are factors in determining a hospital's eligibility for specialized payment categories. Hospitals are not required to have any specific number of inpatients for certification. A hospital's ability to adhere to the inpatient hospital CoPs is not relevant to the reversion to the low-volume hospital payment requirements that were in effect prior to FY 2011.

After consideration of the public comments we received, we are finalizing our proposals, without modification. Consistent with current law, effective beginning FY 2023, the low-volume hospital definition and payment adjustment methodology will revert back to the policy established under statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and extended through subsequent legislation (most recently the Bipartisan Budget Act of 2018).

4. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking, most recently in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45219 through 45221), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment.

Under this previously established process, a hospital makes a written

[214] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-44-Revised-102717.pdf.*

request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and (iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital must refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

As also discussed in the FY 2019 IPPS/LTCH PPS final rule, in addition to the discharge criterion, for FY 2019 and for subsequent fiscal years, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in § 412.101(b)(2)(i) or (iii) for the fiscal year. Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2023, a hospital must be located more than 25 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2023, we proposed that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Specifically, for FY 2023, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2022, in order for the 25-percent, low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2022. If a hospital's written request for low-volume hospital status for FY 2023 is received after September 1, 2022, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2023 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

Under this process, a hospital that qualified for the low-volume hospital payment adjustment for FY 2022 may continue to receive a low-volume hospital payment adjustment for FY 2023 without reapplying if it meets both the discharge criterion and the mileage criterion applicable for FY 2023. As discussed previously, for FY 2023 the discharge and the mileage criteria are reverting to the statutory requirements that were in effect prior to FY 2011, and to the preexisting low-volume hospital qualifying criteria, as implemented in FY 2005 and specified in the existing regulations at § 412.101(b)(2)(i). As in previous years, we proposed that such a hospital must send written verification that is received by its MAC no later than September 1, 2022, stating that it meets the mileage criterion applicable for FY 2023 (that is, is located more than 25 road miles from the nearest ''subsection (d)'' hospital). For FY 2023, we further proposed that this written verification must also state, based upon the most recently submitted cost report, that the hospital meets the discharge criterion applicable for FY 2023 (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges). If a hospital's request for low-volume hospital status for FY 2023 is received after September 1, 2022, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the 25-percent, low-volume, add-on payment adjustment to determine the payment for the hospital's FY 2023 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

We received no comments on our proposed process for requesting and obtaining the low-volume hospital payment adjustment for FY 2023 and therefore are finalizing this proposal without modification.

We note, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41401 and 41702), in accordance with the provisions of section 50204 of the Bipartisan Budget Act of 2018, for FY 2023 and subsequent fiscal years, we made conforming changes to the regulations at 42 CFR 412.101 to reflect that the low-volume payment adjustment policy in effect for these

years is the same low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010. Under these revisions, beginning with FY 2023, consistent with current law, the low-volume hospital qualifying criteria and payment adjustment methodology will return to the criteria and methodology that were in effect prior to the amendments made by the Affordable Care Act (that is, the low-volume hospital payment policy in effect for FYs 2005 through 2010). Therefore, no further revisions to the policy or to the regulations at § 412.101 are required to conform them to the statutory requirement that the low-volume hospital policy in effect prior to the Affordable Care Act will again be in effect for FY 2023 and subsequent years.

D. Changes in the Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

1. Background for the MDH Program

Section 1886(d)(5)(G) of the Act provides special payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).) As discussed in section V.B. of the preamble of this final rule, the MDH program provisions at section 1886(d)(5)(G) of the Act will expire at the end of FY 2022. Beginning with discharges occurring on or after October 1, 2022, all hospitals that previously qualified for MDH status will be paid based on the Federal rate.

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program had been extended by subsequent legislation as follows: section 606 of the ATRA (Pub. L. 112–240) extended the MDH program through FY 2013 (that is, for discharges occurring before October 1, 2013). Section 1106 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) extended the MDH program through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Section 106 of the PAMA (Pub. L. 113–93) extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Section 205 of the MACRA (Pub. L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring before October 1, 2017). Section 50205 of the Bipartisan Budget Act (Pub. L. 115– 123) extended the MDH program through FY 2022 (that is for discharges occurring before October 1, 2022). For additional information on the extensions of the MDH program after FY 2012, we refer readers to the following **Federal Register** documents:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53413 through 53414).
- The FY 2013 IPPS notice (78 FR 14689).
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649).
- The FY 2014 interim final rule with comment period (79 FR 15025 through 15027).
- The FY 2014 notice (79 FR 34446 through 34449).
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50022 through 50024).
- The August 2015 interim final rule with comment period (80 FR 49596).
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57054 through 57057).
- The FY 2018 notice (83 FR 18303 through 18305).
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41429).

2. Expiration of the MDH Program

Because section 50205 of the Bipartisan Budget Act extended the MDH program through FY 2022 only, beginning October 1, 2022, the MDH program will no longer be in effect. Because the MDH program is not authorized by statute beyond September 30, 2022, beginning October 1, 2022, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate.

When the MDH program was set to expire at the end of FY 2012, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405), we revised our sole community hospital (SCH) policies to allow MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions. We codified these changes in the regulations at § 412.92(b)(2)(i) and (v). Specifically, the existing regulations at § 412.92(b)(2)(v) allow for an effective date of an approval of SCH status that is the day following the expiration date of the MDH program. We note that these same conditions apply to MDHs that intend to apply for SCH status with the expiration of the MDH program on September 30, 2022. Therefore, in order for an MDH to receive SCH status effective October 1, 2022, the MDH must apply for SCH status at least 30 days before the expiration of the MDH program; that is, the MDH must apply for SCH status by September 1, 2022. The MDH also must request that, if approved as an SCH, the SCH status be effective with the expiration of the MDH program; that is, the MDH must request that the SCH status, if approved, be effective October 1, 2022, immediately after its MDH status expires with the expiration of the MDH program on September 30, 2022. We emphasize that an MDH that applies for SCH status in anticipation of the expiration of the MDH program would not qualify for the October 1, 2022, effective date for SCH status if it does not apply by the September 1, 2022, deadline. If the MDH does not apply by the September 1, 2022, deadline, the hospital would instead be subject to the usual effective date for SCH classification; that is, as of the date the MAC receives the complete application as specified at § 412.92(b)(2)(i).

We note that the regulations governing the MDH program are found at § 412.108 and the MDH program is also cited in the general payment rules in the regulations at § 412.90. As stated earlier, under current law, the MDH program will expire at the end of FY 2022, which is already reflected in §§ 412.108 and 412.90(j). As such, we did not propose specific amendments to the regulations at § 412.108 or § 412.90 to reflect the expiration of the MDH program. However, we proposed that if the MDH program were to be extended by law, similar to how it was extended through FY 2013, by the ATRA (Pub. L. 112–240); through March 31, 2014, by the Pathway for SGR Reform Act of 2013 (Pub. L. 113–167); through March 31, 2015, by the PAMA (Pub. L. 113–93); through FY 2017, by the MACRA (Pub. L. 114–10); and most recently through FY 2022, by the Bipartisan Budget Act of 2018 (Pub. L. 115–123), we would make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect such an extension of the MDH program. We stated that these conforming changes would only be made if the MDH program were to be extended by statute beyond September 30, 2022. As of the time of the development of this final rule, there has been no change in law to extend the MDH program beyond FY 2022. Therefore, in this final rule, we are not making any additional changes to the regulations governing the MDH program at § 412.108 or the general payment rules at § 412.90.

Comment: Many commenters expressed support for extending the MDH program or making the MDH program permanent and noted that they would continue supporting congressional efforts to protect the MDH program. Some commenters also

expressed support for an additional base year for calculating MDH payments. A commenter urged CMS to remove the MDH program expiration proposal from the final rule. Several state hospital associations expressed their concern that hospitals in their states would experience significant payment decreases as a result of the expiration of the MDH program. A few commenters urged for action to be taken to ensure that the MDH program is extended, while other commenters urged CMS to explore alternatives and make immediate adjustments within its authority to provide relief and mitigate negative impacts to rural hospitals should Congress not act.

Response: While we appreciate the commenters' concerns about the expiration of the MDH program and the financial impact to affected providers if the MDH program is not extended beyond FY 2022, CMS does not have the authority under current law to extend the MDH program beyond the September 30, 2022 statutory expiration date. Similarly, Section 1886(b)(3)(D) of the Act specifies the applicable base years or ''target amounts'' for hospitals classified as MDHs. These comments are similar to comments we received previously, prior to the statutory extension of the MDH program for FY 2018 through FY 2022 provided by subsequent legislation, and discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38220 through 38221). In response to the comment urging CMS to explore other relief options should Congress not act, we will consider this for future rulemaking and explore potential ways to provide support to this subset of rural providers.

Comment: Several commenters expressed support for CMS' policy that allows MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions. Some commenters also requested that CMS also provide former MDHs with the ability to rescind their newly acquired SCH status and reinstate their MDH status in a seamless manner, if a retroactive extension to the MDH program is made.

Response: We appreciate the commenters' support of our policy allowing MDHs to apply for SCH status in advance of the expiration of the MDH program and to be paid as such under certain conditions and allow for a seamless transition from MDH classification to SCH classification. In response to the suggestion that CMS provide former MDHs with ability to rescind their newly acquired SCH status and reinstate their MDH status in a seamless manner if a retroactive extension to the MDH program is made, we understand the desire on the part of hospitals for certainty in the face of MDH program expiration and will consider for future rulemaking any potential mechanisms to further streamline such transitions in connection with legislative extensions of the MDH program. We note that under the current regulations at § 412.108(b)(4), the effective date for MDH classification is as of the date the MAC receives the complete application. A MDH that applied for and was classified as an SCH in advance of the MDH expiration per the regulations at § 412.92(b)(2)(v) could request a cancellation of its SCH status and simultaneously re-apply for MDH status if the MDH program were to be extended, and the MDH classification would be effective as of the date that the MAC receives the complete application. This would allow a former MDH to maintain special payment status as an SCH and then as an MDH generally without interruption in the event the MDH program is extended.

Comment: Commenters urged CMS to expedite restoration of MDH status, should Congress act to extend these programs, stating that past retroactive restorations have seen delays that caused significant cash flow problems to affected hospitals. They requested that CMS move expeditiously to restore payments so that these rural facilities are able to continue to provide quality care to their communities and that CMS clarify how it might handle program extensions, should Congress enact legislation to extend them.

Response: We appreciate the commenters' sharing their concerns relating to a retroactive restoration of the MDH program. As with past extensions, CMS will evaluate enacted legislation to determine the most appropriate approach to implement changes to the law, including instructions to the MACs to reinstate MDH status to eligible hospitals. As in the past, we will make every effort to implement any extension of the MDH program as expeditiously as possible.

In summary, under current law, beginning October 1, 2022, all hospitals that previously qualified for MDH status will no longer have MDH status.

E. Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105)

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35.

Accordingly, for discharges occurring during FY 2023, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2023 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

We did not receive any comments regarding the IME adjustment factor, which, as noted earlier, is statutorily required. Accordingly, for discharges occurring during FY 2023, the IME formula multiplier is 1.35.

F. Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment

known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital (and, for discharges occurring on or after October 1, 1997, at non-provider sites, when applicable) to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital could include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

As mentioned previously, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days. Section 1886(h)(4) of the Act specifies the methodology for determining the amount of FTE residents to be included in a hospital's direct GME payment formula. That is, the number of FTE residents training at a hospital (or in non-provider sites as applicable) would not necessarily equal the sum of those FTE residents used in the hospital's direct GME payment formula, since certain rules and factors are applied to adjust the count of FTE residents for direct GME payment purposes. First, section 1886(h)(4)(C) of the Act requires that a ''weighting factor'' of either 1.0 or 0.5 be applied to each FTE resident, as follows: In calculating the number of FTE residents in an approved residency program on or after July 1, 1987, for a resident who is not in the resident's initial residency period, the weighting factor is 0.50. Section 1886(h)(5)(F) of the Act defines the term ''initial residency period'' as the ''period of board eligibility,'' with certain exceptions. Finally, section 1886(h)(4)(G) of the Act states that the term ''period of board eligibility'' means, for a resident, the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training. The direct GME calculation and our policy on applying the weighting factors to each FTE resident based on the FTE resident's status within or beyond the initial residency period (IRP) was established in the September 29, 1989, **Federal Register** (54 FR 40287, 40292, 40305 and 40306), and implemented in the regulations at 42 CFR 413.86(f) (now 42 CFR 413.79(a) and (b)).

Thus, the FTE count used in the direct GME payment formula must be a weighted FTE count when a hospital is training residents beyond their IRPs. However, the direct GME FTE cap is an unweighted number. That is, under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's *unweighted* FTE count of residents for purposes of direct GME may not exceed the hospital's *unweighted* FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996 (that is the hospital's unweighted 1996 FTE cap or FTE cap). Regulations regarding the FTE caps and unweighted FTE counts were first published in the August 29, 1997, **Federal Register** (62 FR 45966). To address situations where a hospital's weighted FTE count exceeds its unweighted 1996 FTE cap, we established a policy effective for cost reporting periods beginning on or after October 1, 1997, to bring the weighted FTE count within the unweighted FTE cap using the following ratio on the Medicare cost report: ((1996 unweighted FTE cap/current year unweighted FTE count) × (current year total weighted FTE count)) (see 62 FR 46005 and 63 FR 26,330 (May 12, 1998)). In the August 1, 2001, **Federal Register** (66 FR 39893 through 39896), we modified this ratio effective for cost reporting periods beginning on or after October 1, 2001, to separately account for a hospital's current year weighted primary care and obstetrics/gynecology (OB/GYN) FTE count and primary care and OB/GYN PRA, and current year weighted other FTE count and other PRA, as follows: (FTE cap/unweighted total FTEs in the cost reporting period) × (weighted primary care and OB/GYN FTEs in the cost reporting period) plus (FTE cap/unweighted total FTEs in the cost reporting period) × (weighted nonprimary care FTEs in the cost reporting period). The sum of the products is the current year allowable weighted FTE count. In addition, effective for cost reporting periods beginning on or after October 1, 2001, the direct GME payment is calculated using two separate rolling averages, one for primary care and OB/GYN FTE residents, and one for nonprimary care FTE residents. These calculations were implemented at 42 CFR 413.86(g)(4) and (5) respectively, currently 42 CFR 413.79(c)(2)(iii) and (d)(3).

2. Milton S. Hershey Medical Center, et al. v. Becerra Litigation

On May 17, 2021, the U.S. District Court for the District of Columbia ruled against CMS's method of calculating direct GME payments to teaching hospitals when those hospitals' weighted FTE counts exceed their direct GME FTE cap. In *Milton S. Hershey Medical Center, et al.* v. *Becerra* (Slip. Op., 2021 WL 1966572, May 17, 2021), the court ordered CMS to recalculate reimbursement owed, holding that CMS's regulation impermissibly modified the statutory weighting factors discussed previously. The plaintiffs in these consolidated cases alleged that as far back as 2005, the proportional reduction that CMS applied to the weighted FTE count when the weighted FTE count exceeded the FTE cap conflicted with the Medicare statute, and it was an arbitrary and capricious exercise of agency discretion under the Administrative Procedure Act. The Court held that the proportional reduction methodology improperly modified the weighting factors statutorily assigned to residents and fellows. The court ordered CMS to pay the plaintiffs according to a more favorable method.

For example, a hospital has a direct GME cap of 100, trains 90 FTE residents weighted at 1.0 and 10 FTE fellows weighted at 0.5, for a total unweighted

count of 100, and a total weighted FTE count of 95. Under current methodology, the proportional reduction is: (100 cap/100 current year unweighted count) × 95 (current year weighted count) = 95.

If that hospital adds 10 more fellows and exceeds the cap with an unweighted total of 110 (90 residents and 20 fellows), its weighted FTE count of 100 is reduced as follows: (100 cap/110 current year unweighted count) × 100 (current year weighted count) = 90.91.

The plaintiffs stated that CMS's proportional reduction method unlawfully reduced the weighting factor of 0.5 to an amount less than that, thereby reducing the capped weighted FTE amount (100 reduced to 90.91 in the example) to which they were entitled for direct GME payment purposes. The court granted the plaintiffs' motion for summary judgment, denied defendant's, and remanded to the Agency so that it could recalculate plaintiffs' reimbursement payments consistent with the court's opinion. The court held that CMS's proportional reduction methodology, enacted at 42 CFR 413.79(c)(2)(iii), was inconsistent with the statutory weighting factors. In response to the court's decision, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28410 through 28412), we proposed to implement a modified policy applicable to all teaching hospitals, effective as of October 1, 2001, which would replace the existing policy at 42 CFR 413.79(c)(2)(iii). While the proportional reduction method struck down in *Hershey* was first effective for cost reports beginning on or after October 1, 1997, we are unaware of any open or reopenable NPRs for the 1997–2001 period where the proportional reduction method caused a provider's payments to be lower than they would be under our proposed new policy, but we welcomed comments alerting us of such NPRs. The proportional reduction method was amended to its present form effective for cost reporting periods beginning on or after October 2001. (*See* current 42 CFR 413.79(c)(2)(ii) and (iii).) Therefore, we proposed to modify the policy embodied in 42 CFR 413.79(c)(2)(iii), which the Court found in *Hershey* was inconsistent with the statute.

The Court's decision in *Hershey* held that our prior rule governing ''computation of the approved number of full-time equivalent residents in an approved medical residency training program'' (§ 1886(h)(4) of the Act) was inconsistent with the statute. That statute further requires us to ''establish rules consistent with this paragraph'' for the computation of FTEs. Following our review of the district court's reasoning in *Hershey* and the statute, we concluded that our existing formula for computing the number of FTEs was inconsistent with the statutory requirements. It is also our view that the combination of the statutory requirement to ''establish rules'' and the *Hershey* court's conclusion that our existing rules are inconsistent with statutory requirements necessitates a new rulemaking. We further note that the *Hershey* decision does not mandate an alternative payment method, and we do not believe that the decision—or our independent conclusion that the formula should be modified—forecloses alternatives to the calculation method we finalize here. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28411), we stated our belief that, in order to comply with the statutory requirement to make rules governing the computation of FTEs, it is necessary to engage in a retroactive rulemaking to modify the statutorily-required rule effective for cost reporting periods beginning on or after October 1, 2001. While *Hershey* itself does not mandate this conclusion, we believe it would be inconsistent with the statute to calculate past payments for open cost reports based on a rule inconsistent with the law, particularly where a court ordered us to recalculate payments to plaintiffs. Doing so via notice-and-comment rulemaking is in the public interest because it will permit interested stakeholders to comment on the proposed approach, allow the agency to have the benefit of those comments in the development of a final rule, and calculate payments for past open cost years in a transparent, consistent, and efficient manner. This is particularly true in this situation, where the existing policy was promulgated via an interim final rule with comment period, and the agency received no comments on the policy the court found unlawful.

In the proposed rule, we noted that because we proposed to establish this policy retroactively, it would cover cost reporting periods for which many NPRs have already been settled. Consistent with § 405.1885(c)(2), any final rule retroactively adopting the proposed new policy would not be the basis for reopening final settled NPRs.

After reviewing the statutory language regarding the direct GME FTE cap and the court's reasoning, we decided to propose a modified policy to be applied for cost reporting periods beginning on October 1, 2001, as described previously. The proposed modified policy would address situations for applying the FTE cap when a hospital's weighted FTE count was greater than its FTE cap, but would not reduce the weighting factor of residents that are beyond their IRP by an amount less than 0.5. Section 1886(h)(4)(F) of the Act states that for purposes of a cost reporting period beginning on or after October 1, 1997, the total number of FTE residents before application of weighting factors may not exceed the number of such FTEs for the hospital's most recent cost reporting period ending on or before December 31, 1996. Under current policy, we interpreted this to mean that only a hospital's unweighted (before application of weighting factors) allopathic and osteopathic FTE count was compared to its FTE cap, and if the unweighted allopathic and osteopathic FTE count exceeded the FTE cap, then the proportional reduction is made to the weighted FTE counts. Under this modified proposed policy, in the instance where a hospital's unweighted allopathic and osteopathic FTE count exceeds its FTE cap, we proposed to add a step to also compare the total *weighted* allopathic and osteopathic FTE count to the FTE cap. If the total weighted allopathic and osteopathic FTE count is equal to or less than the FTE cap, then no adjustments would be made to the respective primary care & OB/GYN weighted FTE counts or the other weighted FTE counts. If the total weighted allopathic and osteopathic FTE count exceeds the FTE cap, then we would adjust the respective primary care & OB/GYN weighted FTE counts or the other weighted FTE counts to make the total weighted FTE count *equal* the FTE cap, as follows:

((primary care & OB/GYN weighted FTEs/total weighted FTEs) × FTE cap)) + ((other weighted FTEs/total weighted FTEs) × FTE cap)).

The sum would be the current year total allowable weighted FTE count, which would be reported on Worksheet E–4, line 9, column 3.

More specific to the Medicare cost report, we proposed to revise the instructions to Worksheet E–4, line 9 to state: If line 6 is less than or equal to line 5, enter the amounts from line 8, columns 1 and 2, in columns 1 and 2, of this line. Otherwise, *if the total weighted FTE count from line 8, column 3 is greater than the amount on line 5, then enter in column 1 the result of ((primary care & OBGYN weighted FTEs/total weighted FTEs) × FTE cap)). Enter in column 2 the result of ((other weighted FTEs/total weighted FTEs) × FTE cap)). Enter in column 3 the sum of*

((primary care & OBGYN weighted FTEs/total weighted FTEs) × FTE

cap)) + ((other weighted FTEs/total weighted FTEs) × FTE cap)).

Example : [Note—see the comments and responses later in this section for a revised version of this Example 1] Hospital with an FTE cap of 100 trains 120 FTEs with a weight of 1.0, and 105 FTEs with a weight of 0.5, consisting of 70 weighted primary care & OBGYN FTEs and 35 weighted other FTEs. Since the total weighted count of 105 (Worksheet E–4, line 8, column 3) exceeds the FTE cap of 100 (Worksheet E–4, line 5), the Hospital reports the following adjusted weighted FTE counts on Worksheet E–4:

Line 9, column 1: ((70 weighted primary care & OBGYN FTEs/105 total weighted FTEs) × 100 cap)) = 66.67.

Line 9, column 2: ((35 weighted other FTEs/105 total weighted FTEs) × 100 cap)) = 33.33.

Line 9, column 3: 66.67 FTEs + 33.33 FTEs = 100.

Example 2: Hospital with an FTE cap of 100 trains 102 unweighted FTEs, equating to 96 weighted FTEs. This 96-weighted count consists of 30 weighted primary care & OBGYN FTEs, and 66 weighted other FTEs. Since the total weighted count of 96 (Worksheet E–4, line 8, column 3) is less than the FTE cap of 100 (Worksheet E–4, line 5), then no further adjustment is needed; enter the amounts from line 8, columns 1 and 2, in columns 1 and 2, of line 9.

Example 3: Hospital with a cap of 100 FTEs trains 90 FTEs with a weight of 1.0, and 20 FTEs with a weight of 0.5. Since the total weighted count is 100 (90 + (20 × 0.5)), then no further adjustment is needed. Enter the amounts from line 8, columns 1 and 2, in columns 1 and 2 of line 9.

Comment: We received many comments supporting our proposed revision to the weighted count methodology and to the Medicare cost reporting instructions. Commenters urged CMS to finalize the proposed revision, asserting it is required by the law and the court's order, and to recalculate payments immediately, as over a year has passed since the court order.

Response: We appreciate the commenters' support, and upon issuance of this final rule, we will work with the MACs and other impacted parties to recalculate and issue adjusted payments as soon as possible.

Comment: Many commenters urged CMS to abandon the proposal to use retroactive rulemaking as the means of complying with the decision of the Hershey court. These commenters stated that retroactive rulemaking is strongly disfavored under the Medicare statute and permitted only under limited circumstances as specified in section 1871(e)(1)(A) of the Act, namely, when it is either necessary to comply with statutory requirements (§ 1871(e)(1)(A)(i)) of the Act); or when failure to apply the change retroactively would be contrary to the public interest (§ 1871(e)(1)(A)(ii) of the Act). Commenters asserted that neither of these exceptions applies in the present case.

With respect to the exception at section 1871(e)(1)(A)(i) of the Act, commenters stated that retroactive rulemaking is not necessary for CMS to comply with statutory requirements. Commenters said that the Medicare statute is unambiguous with respect to the weighting of residents and fellows, and that the proposed revision to the methodology is the only way for CMS to comply with the statutory directive and the Hershey decision, neither of which requires any interpretation by the agency. Commenters also stated that the exception at section 1871(e)(1)(A)(ii) does not apply, since it does not serve the public interest for CMS to engage in retroactive rulemaking and to entertain public comments on actions that the agency is required to take under a legally binding court order. According to a commenter, engaging in retroactive rulemaking in this instance implicitly contradicts the court's decision, while others expressed concern that it would create a precedent whereby CMS might invoke public interest in receiving comments as a justification for virtually any retroactive rule change. Commenters also stated that it is not necessary for CMS to engage in retroactive rulemaking to benefit from public comments, pointing out that in the past the agency has made retroactive policy changes via program instruction and only submitted the policies to public comment for purposes of prospective application.

Commenters also rejected the argument that retroactive rulemaking in this instance is necessary to comply with the Supreme Court's ruling in *Azar* v. *Allina Health Services.* Commenters observed that the Allina ruling established the need for notice-and-comment rulemaking to change a substantive legal standard governing payment where the agency engages in ''gap-filling'' an ambiguous statute. However, as previously stated, commenters believed that the statute is unambiguous with regard to the weighting of residents and fellows, and that therefore there are no gaps for the agency to fill. In other words, as stated by a commenter, the proposed policy is already dictated by the statute as explained in Hershey, and there is no room for CMS to substantively change the policy enacted by Congress.

Furthermore, commenters disagreed with CMS's position, as originally stated in the FY 2023 IPPS/LTCH proposed rule, that retroactive rulemaking is necessary in the wake of the Hershey ruling since the Secretary ''has no promulgated rule governing'' direct GME payments to teaching hospitals over the cap for cost reporting periods beginning on or after October 1, 2001 (87 FR 28411). A number of commenters stated that the Hershey court did not leave CMS with a regulatory void to fill, but merely ruled ''that the regulation is unlawful as applied to the Plaintiffs''; even if the court had vacated the existing regulation, these commenters asserted that notice-and-comment rulemaking would not be required or appropriate to acquiesce to the vacatur. By contrast, another commenter stated that the existing regulation is a ''legal nullity'' in light of the Hershey decision, but nevertheless stated that the statutory payment directive requires no substantive change in policy and can be properly effectuated without rulemaking.

Citing a number of examples, commenters observed that historically, both before and after Allina, CMS has implemented policy changes to resolve appeals or comply with court decisions without engaging in retroactive rulemaking, and invoked its retroactive rulemaking authority only under particular circumstances, such as in response to a natural disaster or when a rule is published after a statute's effective date. Only more recently, according to commenters, has CMS inappropriately begun to engage in retroactive rulemaking in response to litigation. Rather than engage in retroactive rulemaking to comply with the Hershey decision, commenters urged CMS to make the change in regulation prospectively and to employ other appropriate means, such as program instruction to the MACs or settlement with hospitals, to implement the proposed correction for past years.

While urging CMS to abandon retroactive rulemaking as the means of complying with the Hershey decision, commenters stated that, if CMS does engage in retroactive rulemaking, it should specify exactly which hospitals and past cost reporting periods will be eligible for relief under the revised policy. In particular, commenters pointed out that CMS proposed that ''certain other providers'' will be eligible for relief in addition to the plaintiffs in Hershey, but the preamble does not make it clear who those

providers will be. These commenters stated that CMS should reopen all cost reports within the three-year reopening period and recalculate direct GME payments consistent with the statute. At a minimum, however, the ''certain other providers'' should include any provider that, if applicable, has an appeal pending with the Provider Reimbursement Review Board or in federal court on the same issue as Hershey. In addition, if CMS does not reopen all cost reports that are within the three-year reopening period, it should nonetheless apply the methodology any time a cost report is reopened and the direct GME payment is altered. Other commenters likewise stated that hospitals should be permitted to reopen their cost reports for the purpose of recalculating their direct GME payments according to the revised weighting methodology, and that CMS should not finalize any ongoing cost report audits until the final rule has been issued.

Some commenters expressed concern that CMS's proposal to extend relief to only certain providers is inconsistent with concept of retroactive rulemaking. Another commenter objected to CMS's statement that under 42 CFR 405.1885(c)(2), any final rule retroactively adopting the proposed new policy would not be the basis for reopening final settled NPRs (87 FR 28411). This commenter asserted that § 405.1885(c)(2) does not apply to retroactive rulemaking, and that CMS's proposal has ''no real retroactive effect'' if it does not serve as the basis for reopening settled cost reports. Another commenter similarly recommended that CMS make the new policy ''fully retroactive'' so that even final settled NPRs subject to reopening may be reopened for the purpose of applying the revised methodology. This commenter stated that withholding relief from certain providers would be arbitrary and capricious and result in CMS not fully complying with the statute.

Response: We appreciate the comments regarding our proposal to implement the court's decision in *Hershey* retroactively, but for the reasons that follow (as well as those stated in the proposed rule), we are finalizing our policy as proposed, retroactive to 2001.

We agree with commenters who objected to our statement that there is ''no promulgated rule governing'' direct GME payments to over-the-cap hospitals. The *Hershey* court did not vacate the rule. We further agree that the *Hershey* decision itself does not require us to engage in retroactive rulemaking. However, the statute at issue states that ''[t]he Secretary shall establish rules *consistent with this paragraph* for the computation of the number of full-time equivalent residents in an approved medical residency training program.'' Section1886(h)(4)(A) of the Act (emphasis added). And the *Hershey* court did say that the rules at issue were not consistent with the statute. Following our review of the *Hershey* court's reasoning and the statutory requirements, we decided that our method for computing FTEs was not consistent with statutory requirements. We therefore conclude that our existing rule, which does not comply with the statute, should be modified retroactively such that our FTE computation rules are consistent with the statute and payments, including payments for open cost years in past, are calculated pursuant to regulation.

Several commenters state that no rule is necessary because of an express statutory mandate that fellows be counted as 0.5 FTE. We disagree, for two reasons. First, there are two express statutory mandates in the section cited by commenters: that the Secretary promulgate rules, and that those rules weight fellows at 0.5 FTE (see sections 1886(h)(4)(A) and 1886(h)(4)(C)(iv) of the Act). In other words, the statutory language cited by commenters describes the content of the rules the Secretary is required to promulgate, rather than setting an independent statutory benchmark. Second, we disagree with the commenters' position that the rule we proposed was the only possible way to compute FTE counts in light of *Hershey*. Section 1886(h)(4)(C) is not the only relevant statutory provision governing the content of the rule; section 1886(h)(4)(F)(i) of the Act requires the rules to cap the number of unweighted residents based on a hospital's FY 1996 FTE count. In *Hershey* itself, the court did not mandate a particular method of calculation or require CMS to adopt the plaintiffs' proposed calculation method. We believe that there is more than one way to comply with the statutory requirements and the court's order. Our decision in this rule does not mean that all other alternatives were foreclosed by the *Hershey* decision. The *Hershey* court decision held that the prior regulation governing FTE counting for over-the-cap hospitals was unlawful. It did not mandate any particular alternative approach. We further disagree with commenters to the extent they suggest that we compute FTE counts without a rule in place for doing so. As discussed elsewhere, the statute at issue requires the Secretary to establish a rule.

Even if the *Hershey* decision did mandate a single method of computing FTE counts, it was silent on how to incorporate that computation into the three-year rolling average. Without a rule for determining the inputs to the three-year-rolling average, which we proposed and are now finalizing, it is impossible to calculate a given provider's dollar reimbursement. Therefore, even if we agreed with commenters that the *Hershey* decision provided sufficient guidance for computing FTE counts and that no further rulemaking on that issue is required, we would nonetheless consider it necessary to undergo rulemaking to implement our response to the decision, that is, use its requirements to develop a method for calculating reimbursement. For these reasons, we disagree with commenters who believe that notice-and-comment rulemaking is unnecessary to implement the Hershey decision, including for past cost years.

We appreciate the comments about retroactive rulemaking here being inconsistent with CMS's historical practice. Many of the examples raised by commenters do not involve judicial decisions calling into question agency rules, which is a key factor here, as we noted in the proposed rule. The governing statute requires the Secretary to promulgate rules governing reimbursement that are consistent with statutory requirements, and the court's decision in *Hershey* concluded that our existing rule was not consistent with those requirements. We do not believe that using retroactive rulemaking in this instance is inconsistent with our past practice.

We acknowledge that our statutory authority to engage in retroactive rulemaking is limited by section 1871(e)(1)(A) of the Act. As previously discussed, we believe that the explicit statutory requirement that the Secretary promulgate a rule governing GME reimbursement renders retroactive application here ''necessary to comply with statutory requirements.'' 1871(e)(1)(A)(i). If we promulgated this rule prospectively only, a necessary result would be that some hospitals would receive GME reimbursement based on a computation of FTE equivalents that was not established by rule. We emphasize again that the rule at issue in *Hershey* and the rule we promulgate here are not merely statutory gap-fillers. The statute affirmatively requires us to promulgate a rule.

In the alternative, and even if it were permissible to compute the number of FTEs without a rule governing the methodology for doing so, we believe that retroactive rulemaking here is in the public interest (section 1871(e)(1)(A)(ii) of the Act). In response to comments, we want to make clear that we believe that public notice-and-comment will benefit the rulemaking process generally. As we noted in the preamble, there was limited public comment on the key provisions of the original rulemaking that the *Hershey* court found inconsistent with statutory requirements. And we acknowledge—and we do not believe that commenters disagree—that it is necessary to recalculate past payments in light of the Hershey decision. The public interest will be served by having past payments calculated in the same way as future payments, and given our view that it is necessary to engage in notice-and-comment rulemaking to implement the Hershey decision, we believe it is sensible and efficient to calculate past payments based on a formula promulgated with the benefit of notice-and-comment rulemaking. We do not mean to imply that the public interest requires consistency between past payments and future payments in all conceivable situations. However, where—as here— payment was set by a regulation that a court held inconsistent with substantive statutory requirements and the agency engages in new notice-and-comment rulemaking to implement that judicial ruling, there is a public benefit in having past payments calculated via the same method as future payments. This is particularly true where the statute at issue requires that payments be calculated pursuant to a rule. We therefore believe that this is a case where the public interest in having a rule applicable to all payments, both past and future, justifies retroactive rulemaking. It would be contrary to the public interest for plaintiffs in *Hershey* and other judicial challenges to have their payments calculated by a different methodology (whether more or less generous than the methodology established by regulation) than other providers that are otherwise similarly situated. Retroactive rulemaking in this situation, benefits the public interest by achieving parity in payment among similarly situated hospitals.

We also believe that the public interest is served by having payments for past open cost years calculated in a transparent, efficient, and not administratively burdensome fashion, an interest that is served by promulgating a rule (following notice-and-comment) that applies to those cost years. This rule will allow us to calculate payments to hospitals with open cost reports based on a universal and transparent formula, and it will allow many hospitals (and MACs) to avoid the administrative expense of calculating payments based on a formula that the agency has concluded should not be applied. The public interest is further served by reducing the need for hospitals to file administrative appeals in order to obtain the benefit of the new payment formula.

We appreciate comments regarding the applicability of 42 CFR 405.1885(c)(2) to this rule. We disagree that 405.1885(c)(2) does not apply to retroactive rules. The text of the regulation does not support that proposed carve-out. The rule we proposed—and finalize here—is a ''change of legal interpretation or policy by CMS in a regulation . . . made in response to judicial precedent,'' and thus it is ''not a basis for reopening a CMS or contractor determination.'' Some commenters urged us to apply 42 CFR 405.1885(c)(1) to direct contractors to reopen cost reports, but we note that paragraph (c)(1) allows CMS to do so (''CMS may direct a contractor . . . to reopen and revise'') subject to the prohibited reopening's in paragraph (c)(2). We disagree that this rule will have no ''real retroactive effect,'' as a number of hospitals will receive increased reimbursement for past cost reporting years.

We further disagree that it is arbitrary and capricious to apply 405.1885(c)(2) here. This is not the first time that we have made a policy change that could potentially affect closed cost reports, and we have previously declined to direct reopening of closed cost reports consistent with the policy favoring finality embedded in 405.1885(c)(2). For example, we permitted qualifying hospitals to request application of a policy change made in the FY 2020 IPPS rule to FYs 2011 through 2017, ''subject to the reopening rules at 42 CFR 405.1885.'' (84 FR 42349) We believe that the policy we finalize here is consistent with our past practice and our general approach toward finality.

Comment: Many commenters appreciated that CMS proposed that ''If the number of FTE residents weighted in accordance with paragraph (b) of this section does not exceed [the FTE cap], then the allowable weighted FTE count is the actual weighted FTE count.'' However, some commenters pointed out that CMS's proposed change to the instructions for line 9 of Worksheet E–4 does not contain language reflecting this scenario and requested that CMS add a third sentence to the proposed changes to the instructions for line 9. The sentence should state as follows: ''If the total weighted FTE count from line 8, column 3 is less than or equal to the amount on line 5, then enter the amounts from line 8, columns 1 and 2, in columns 1 and 2 of this line.''

Response: We agree with the commenters' request and will revise the proposed instructions to Worksheet E–4, line 9 to address the commenters' request. However, since we are adding the sentence requested by the commenters, then we are removing the following: ''*If line 6 is less than or equal to line 5, enter the amounts from line 8, columns 1 and 2, in columns 1 and 2, of this line.*'' This latter sentence is not necessary, since if line 6 is less than or equal to line 5, then by default line 8, column 3 will also be less than or equal to line 5. We are revising the instructions to Worksheet E–4, line 9 to state: *If the total weighted FTE count from line 8, column 3 is less than or equal to the amount on line 5, then enter the amounts from line 8, columns 1 and 2, in columns 1 and 2 of this line (emphasis added). Otherwise, if the total weighted FTE count from line 8, column 3 is greater than the amount on line 5, then enter in column 1 the result of ((primary care & OBGYN weighted FTEs/total weighted FTEs) × FTE cap)). Enter in column 2 the result of ((other weighted FTEs/total weighted FTEs) × FTE cap)). Enter in column 3 the sum of columns 1 and 2.*

Under section 1886(h)(4)(G)(i) and 42 CFR 413.79(d)(3), a hospital's weighted FTE count for payment purposes is the 3-year average of its current year weighted FTEs, prior year weighted FTEs, and penultimate year FTEs (for primary care & OBGYN FTEs and other FTEs respectively). Effective for cost reporting periods beginning on or after October 1, 2001, we proposed to implement this modified methodology for the purpose of determining the prior year weighted FTE count on line 12 of Worksheet E–4, and for the purpose of determining the penultimate year's weighted FTE count on line 13 of Worksheet E–4, even though the prior and penultimate years' FTE counts would be from cost reporting periods prior to October 1, 2001. In this manner, the modified methodology would be fully applied to determining the direct GME payment for cost reporting periods beginning on or after October 1, 2001.

Therefore, we proposed to modify the cost report instructions on Worksheet E–4, lines 12 and 13, respectively to state that effective for cost reporting periods beginning on or after October 1, 2001, if subject to the cap in the prior

year or penultimate year respectively, *if the prior/penultimate year total weighted FTE count from line 8, column 3 is greater than the amount on line 5 from the prior/penultimate year, then enter in column 1 the result of ((primary care & OBGYN weighted FTEs/total weighted FTEs) × FTE cap)). Enter in column 2 the result of ((other weighted FTEs/total weighted FTEs) × FTE cap)) plus the amount on line 10, column 2.* These instructions do not in any way modify or reopen final-settled prior and penultimate year NPRs.

Comment: Some commenters supported CMS's proposal to update the cost report instructions for lines 12 and 13 of Worksheet E–4 to ensure that the weighted resident FTE counts from the prior and penultimate years will be updated to reflect the new direct GME payment formula. However, the commenters pointed out that the proposed language for lines 12 and 13 does not specify how to calculate the weighted FTE count for the prior and/or penultimate years when the unweighted FTE count from those years exceeds the FTE cap, but the weighted FTE count from those years does not, and requested that CMS add a sentence to the instructions for lines 12 and 13 stating: ''If the prior/penultimate year total weighted FTE count from line 8, column 3 is less than or equal to line 5 from the prior/penultimate year, then enter the amounts from line 8, columns 1 and 2, in columns 1 and 2 of this line.''

Response: We agree with the commenters' request and are revising the instructions on Worksheet E–4 lines 12 and 13 to state: *Effective for cost reporting periods beginning on or after October 1, 2001, if the prior/penultimate year total weighted FTE count from line 8, column 3 is less than or equal to line 5 from the prior/penultimate year, then enter the amounts from line 8, columns 1 and 2, in columns 1 and 2 of this line (emphasis added). If subject to the cap in the prior year or penultimate year respectively, if the prior/penultimate year total weighted FTE count from line 8, column 3 is greater than the amount on line 5 from the prior/penultimate year, then enter in column 1 the result of ((primary care & OBGYN weighted FTEs/total weighted FTEs) × FTE cap)). Enter in column 2 the result of ((other weighted FTEs/total weighted FTEs) × FTE cap)) plus the amount on line 10, column 2.*

Comment: Several commenters observed that CMS should have also proposed to apply the revised direct GME weighting methodology to the so-called ''section 422 MMA (Medicare Modernization Act) cap slots'' as well. Specifically, many teaching hospitals received additional FTE caps following a redistribution of unused FTE cap slots mandated by section 422 of the MMA. Similar to the fellowship penalty, CMS applies a proportional methodology when determining payment for section 422 cap FTEs. The commenters suggested that CMS calculate the ''Section 422 Allowable Direct GME FTE Resident Count'' on Worksheet E–4, line 22 as follows:

- If the weighted FTEs on line 8 are less than or equal to the adjusted FTE cap on line 5, the hospital would have entered the weighted FTEs from line 8 on line 9. In this instance, the additional section 422 cap slots are unnecessary, and the hospital would enter zero on line 22.
- If the weighted FTEs on line 8 are greater than the adjusted FTE cap on line 5, the hospital would have entered the adjusted FTE cap on line 9. In this instance, the hospital would subtract line 9 from line 8 and proceed as follows:
  - If line 9 minus line 8 equals or exceeds the ''Section 422 Direct GME FTE Cap'' on line 20, then the hospital would enter the amount from line 20 on line 22.
  - If line 9 minus line 8 is less than line 20, the hospital would enter line 9 minus line 8 on line 20.

Response: We agree with the commenters' observation that the revised methodology should apply to the MMA section 422 FTE cap, as the mathematical cap concept is the same for the 422 FTE cap as it is for the regular FTE cap. Accordingly, for portions of cost reporting periods beginning on or after July 1, 2005, the effective date of section 422 under 42 CFR 413.79(c)(4), we will revise Worksheet E–4, line 22, as follows:

For portions of cost reporting periods beginning on or after July 1, 2005, if the weighted FTE count on line 8 is less than or equal to the adjusted FTE cap on line 5, the hospital would have entered the weighted FTEs from line 8 on line 9. In this instance, the additional § 422 cap slots are unnecessary; do not complete lines 22 through 24. If the weighted FTE count on line 8 is greater than the adjusted FTE cap on line 5, the hospital would have entered the adjusted FTE cap on line 9. In this instance, subtract line 9 from line 8. If line 9 minus line 8 equals or exceeds the ''Section 422 Direct GME FTE Cap'' on line 20, then enter the amount from line 20 on line 22. If line 9 minus line 8 is less than line 20, enter line 9 minus line 8 on line 22. (We note the commenters indicated ''enter line 9 minus line 8 on line 20,'' but we believe they meant to say ''on line 22'').

We proposed to amend the regulations text at 42 CFR 413.79(c)(2)(iii) to state that, effective for cost reporting periods beginning on or after October 1, 2001, if the hospital's unweighted number of FTE residents exceeds the limit described in this section of the final rule, and the number of weighted FTE residents in accordance with § 413.79(b) also exceeds that limit, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the limit. If the number of FTE residents weighted in accordance with § 413.79(b) does not exceed that limit, then the allowable weighted FTE count is the actual weighted FTE count.

Comment: A commenter requested that CMS make conforming changes to the three-year rolling average regulation at. § 413.79(d)(3) to clarify that the weighted FTE counts for the ''preceding two cost reporting periods'' must be calculated in accordance with the revised payment formula at § 413.79(c)(2)(iii).

Response: We agree to add a parenthetical to the regulations at § 413.79(d)(3) to state, ''For cost reporting periods beginning on or after October 1, 2001, the hospital's weighted FTE counts for the preceding two cost reporting periods are calculated in accordance with the payment formula at 42 CFR 413.79(c)(2)(iii)).''

Comment: A commenter stated they would like to see the three-year rolling average eliminated retroactive to October 1, 2001, as it would delay implementation of CMS's proposed payment formula.

Response: Under section 1886(h)(4)(G)(i) and 42 CFR 413.79(d)(3), a hospital's weighted FTE count for payment purposes is the 3-year average of its current year weighted FTEs, prior year weighted FTEs, and penultimate year weighted FTEs (for primary care & OBGYN FTEs and other FTEs respectively). Our proposed interpretation of section 1886(h)(4)(F) of the Act regarding application of weighting factors does not change this portion of the statute regarding application of the 3-year rolling average. Therefore, we are not adopting the commenter's request to eliminate application of the rolling average under our proposed payment formula.

Comment: Some commenters requested that CMS correct or clarify certain misstatements in the FY 2023 IPPS/LTCH PPS proposed rule regarding the *Hershey* case. First, CMS should be clearer about the position of the *Hershey*

plaintiffs. CMS described the position of the *Hershey* plaintiffs as follows: ''The plaintiffs in these consolidated cases alleged that as far back as 2005, the proportional reduction that CMS applied to the weighted FTE count when the weighted FTE count exceeded the FTE cap conflicted with the Medicare statute'' (87 FR 28410). According to the commenters, this is an incomplete description of the plaintiffs' position. The commenters stated that CMS's proportional reduction also impermissibly reduces the weighted FTE count when the weighted FTE count is less than unweighted FTE cap.

Second, the commenters believed that ''Example 1'' in the preamble is misstated. In that example, a ''Hospital with an FTE cap of 100 trains 120 FTEs with a weight of 1.0 and 105 FTEs with a weight of 0.5, consisting of 70 weighted primary care & OBGYN FTEs and 35 weighted other FTEs'' (87 FR 28411). The ''total weighted count'' is ''105.'' The commenters noted that if the hospital trained 120 FTEs with a weight of 1.0 and 105 FTEs with a weight of 0.5, its unweighted FTE count would be 225 (120 + 105), and its weighted FTE count would be 172.5 ((120 × 1.0) + (105 × 0.5)), not 105. The commenters believed that CMS intended this example to say that the hospital had an unweighted FTE count of 120 and a weighted FTE count of 105. The 105 weighted FTEs would consist of 90 FTEs weighted at 1.0 and 30 FTEs weighted at 0.5.

Response: Regarding the first point about not fully capturing Plaintiffs' position, we acknowledge the commenters' assertion that the plaintiffs in *Hershey* argued that CMS's proportional reduction impermissibly reduced the weighted FTE count when the weighted FTE count was less than unweighted FTE cap.

Regarding the second point that the commenters believe that Example 1 is misstated, we acknowledge the confusing wording, and we are providing a corrected Example 1 as follows:

Example 1 Revised: Hospital with an FTE cap of 100 trains 120 unweighted FTEs, consisting of 105 weighted FTEs (90 FTEs weighted at 1.0 and 30 FTEs weighted at 0.5 = 105 weighted FTEs). The 105 weighted FTEs further consists of 70 weighted primary care & OBGYN FTEs and 35 weighted other FTEs. Since the total weighted count of 105 (Worksheet E–4, line 8, column 3) exceeds the FTE cap of 100 (Worksheet E–4, line 5), the Hospital reports the following adjusted weighted FTE counts on Worksheet E–4:

Line 9, column 1: ((70 weighted primary care & OBGYN FTEs/105 total weighted FTEs) × 100 cap)) = 66.67.

Line 9, column 2: ((35 weighted other FTEs/105 total weighted FTEs) × 100 cap)) = 33.33.

Line 9, column 3: 66.67 FTEs + 33.33 FTEs = 100.

Comment: A commenter requested clarification on the implications of the Medicare direct GME formula change for hospitals that participate in the Children's Hospitals Graduate Medical Education (CHGME) program administered by HRSA.

Response: Since the CHGME program is administered by HRSA and not by CMS, we defer to HRSA to determine the implications of CMS's change to the Medicare direct GME payment formula.

After consideration of comments received, we are finalizing our proposed policy and regulations text at 42 CFR 413.79(c)(2)(iii) to state that, effective for cost reporting periods beginning on or after October 1, 2001, if the hospital's unweighted number of FTE residents exceeds the limit described in this section of the final rule, and the number of weighted FTE residents in accordance with § 413.79(b) also exceeds that limit, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the limit. If the number of FTE residents weighted in accordance with § 413.79(b) does not exceed that limit, then the allowable weighted FTE count is the actual weighted FTE count. In response to comments, we are also making a conforming change to the regulations text at 42 CFR 413.79(d)(3) regarding application to the 3-year rolling average to state that for cost reporting periods beginning on or after October 1, 2001, the hospital's weighted FTE counts for the preceding two cost reporting periods are calculated in accordance with the payment formula at § 413.79(c)(2)(iii). In addition, in response to comments, we are applying the new payment methodology to the MMA section 422 FTE cap.

3. Reasonable Cost Payment for Nursing and Allied Health Education Programs

a. General

Under section 1861(v) of the Act, Medicare has historically paid providers for Medicare's share of the costs that providers incur in connection with approved educational activities. Approved nursing and allied health (NAH) education programs are those that are, in part, operated by a provider, and meet State licensure requirements, or are recognized by a national accrediting body. The costs of these programs are excluded from the definition of inpatient hospital operating costs and are not included in the calculation of payment rates for hospitals or hospital units paid under the IPPS, IRF PPS, or IPF PPS, and are excluded from the rate-of-increase ceiling for certain facilities not paid on a PPS. These costs are separately identified and ''passed through'' (that is, paid separately on a reasonable cost basis). Existing regulations on NAH education program costs are located at § 413.85. The most recent rulemakings on these regulations were in the January 12, 2001 final rule (66 FR 3358 through 3374), and in the August 1, 2003, final rule (68 FR 45423 and 45434).

b. Medicare+Choice Nursing and Allied Health Education Payments

Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 provides for additional payments to hospitals for costs of nursing and allied health education associated with services to Medicare+Choice (now called Medicare Advantage (MA)) enrollees. Hospitals that operate approved nursing or allied health education programs and receive Medicare reasonable cost reimbursement for these programs would receive additional payments from MA organizations. Section 541 of the BBRA limits total spending under the provision to no more than $60 million in any calendar year (CY). (In this document, we refer to the total amount of $60 million or less as the payment ''pool''.) Section 541 of the BBRA also provides that direct graduate medical education (GME) payments for Medicare+Choice utilization are reduced to the extent that these additional payments are made for nursing and allied health education programs. This provision was effective for portions of cost reporting periods occurring in a CY, on or after January 1, 2000.

Section 512 of the Benefits Improvement and Protection Act (BIPA) of 2000 changed the formula for determining the additional amounts to be paid to hospitals for MA nursing and allied health costs. Under section 541 of the BBRA, the additional payment amount was determined based on the proportion of each individual hospital's nursing and allied health education payment to total nursing and allied health education payments made to all hospitals. However, this formula did not account for a hospital's specific MA utilization. Section 512 of the BIPA revised this payment formula to specifically account for each hospital's

MA utilization. This provision was effective for portions of cost reporting periods occurring in a calendar year, beginning with CY 2001, and was implemented in the August 1, 2001 IPPS final rule (66 FR 39909 and 39910).

The regulations at 42 CFR 413.87 codified both statutory provisions. We first implemented the BBRA NAH MA provision in the August 1, 2000 IPPS interim final rule with comment period (IFC) (65 FR 47036 through 47039). In that IFC, we outlined the qualifying conditions for a hospital to receive the NAH MA payment, how we would calculate the NAH MA payment pool, and how a qualifying hospital would calculate its ''share'' of payment from that pool. Determining a hospital's NAH MA payment essentially involves applying a ratio of the hospital-specific NAH Part A payments, total inpatient days, and MA inpatient days, to national totals of those same amounts, from cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year. The formula is as follows:

(((Hospital NAH pass-through payment/ Hospital Part A Inpatient Days) * Hospital MA Inpatient Days)/ ((National NAH pass-through payment/National Part A Inpatient Days) * National MA Inpatient Days)) * Current Year Payment Pool.

With regard to determining the total national amounts for NAH pass-through payment, Part A inpatient days, and MA inpatient days, we note that section 1886(l) of the Act, as added by section 541 of the BBRA, gives the Secretary the discretion to ''estimate'' the national components of the formula noted previously. For example, section 1886(l)(2)(A) of the Act states that the Secretary would estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under subsection 1886(h)(3)(D) to total direct GME payments estimated for the same portions of periods under subsection 1886(h)(3) of the Act. Accordingly, we made the following statements in the August 1, 2000 IFC:

- Each year, we would determine and publish in a final rule and a final rule the total amount of nursing and allied health education payments made across all hospitals during the fiscal year that is 2 years prior to the current calendar year (65 FR 47038). We would use the best available cost reporting data for the applicable hospitals from the Hospital Cost Report Information System (HCRIS) for cost reporting periods in the fiscal year that is 2 years prior to the current calendar year (65 FR 47038).
- To calculate the pool, in accordance with section 1886(l) of the Act, we would ''estimate'' a total amount for each calendar year, not to exceed $60 million (65 FR 47038).
- To calculate the proportional reduction to Medicare+Choice (now MA) Direct GME payments, we stated that the percentage is estimated by calculating the ratio of the Medicare+Choice nursing and allied health payment ''pool'' for the current calendar year to the projected total Medicare+Choice direct GME payments made across all hospitals for the current calendar year. We stated that the projections of Medicare+Choice direct GME and Part A direct GME are based on the best available cost report data from the HCRIS (for example, for calendar year 2000, the projections are based on the best available cost report data from HCRIS 1998), and these payment amounts were increased using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for Medicare+Choice direct GME and the Consumer Price Index (CPI) increases for Part A direct GME). We also stated that we would publish the applicable percentage reduction each year in the IPPS proposed and final rules (65 FR 47038).

Thus, in the August 1, 2000, IFC, we described our policy regarding the timing and source of the national data components for the NAH MA add-on payment and the percent reduction to the direct GME MA payments, and we stated that we would publish the rates for each calendar year in the IPPS proposed and final rules. While the rates for CY 2000 were published in the August 1, 2000, IFC (see 65 FR 47038 and 47039), the rates for subsequent CYs were only issued through Change Requests (CRs) (CR 2692, CR 11642, CR 12407). After recent issuance of the CY 2019 rates in CR 12407 on August 19, 2021, we reviewed our update procedures, and were reminded that the August 1, 2000 IFC states that we would publish the NAH MA rates and direct GME percent reduction every year in the IPPS rules. Accordingly, for CY 2020 and forward, the NAH MA add-on rates will be proposed and included in the IPPS proposed and final rules, and we are also reiterating the data sources we would use.

In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed the NAH MA add-on rates as well as the direct GME MA percent reductions for CYs 2020 and 2021. We proposed to issue the rates for CYs 2020 and 2021 because we believe we have sufficient HCRIS data to develop the rates for these years, and these rate years are most needed to ensure accurate and timely cost report settlements of cost reports with portions overlapping with CYs 2020 and 2021. We expect to propose to issue the rates for CY 2022 in the FY 2024 IPPS/LTCH PPS proposed rule, and the rates for CY 2023 in the FY 2025 IPPS/LTCH PPS proposed rule, and so forth.

Consistent with the use of HCRIS data for past calendar years, for CY 2020, we proposed to use data from cost reports ending in FY 2018 HCRIS (the fiscal year that is 2 years prior to CY 2020) to compile these national amounts: NAH pass-through payment, Part A Inpatient Days, MA Inpatient Days. We proposed to use data from cost reports ending in FY 2019 HCRIS (the fiscal year that is 2 years prior to CY 2021) to compile the same national amounts for CY 2021.

For the proposed rule, we accessed the HCRIS data from the fourth quarterly HCRIS update of 2021. However, to calculate the ''pool'' and the direct GME MA percent reduction, we ''project'' Part A direct GME payments and MA direct GME payments for the current calendar years, which in this final rule, are CYs 2020 and 2021, based on the ''best available cost report data from the HCRIS'' (65 FR 47038). Next, consistent with the method we described previously from the August 1, 2000 IFC, we increased these payment amounts from midpoint to midpoint of the appropriate calendar year using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME, and the Consumer Price Index–Urban (CPI–U) increases for Part A direct GME. For CY 2020, the direct GME projections are based on FY 2019 HCRIS. For CY 2021, the direct GME projections are based on FY 2019 HCRIS. For CYs 2020 and 2021, the proposed national rates and percentages, and their data sources are set forth in this table. We stated in the proposed rule that we intend to update these numbers in the FY 2023 final rule based on the latest available cost report data.

	CY 2020	SOURCE	CY 2021	SOURCE
NAH Pass-Through	$272,775,476	Cost reports ending in FY 2018 HCRIS	$277,240,471	Cost reports ending in FY 2019 HCRIS
Part A Inpatient Days	64,510,859	Cost reports ending in FY 2018 HCRIS	66,521,096	Cost reports ending in FY 2019 HCRIS
MA Inpatient Days	9,481,755	Cost reports ending in FY 2018 HCRIS	10,705,665	Cost reports ending in FY 2019 HCRIS
Part A Direct GME	$2,770,987,049	CY 2019 HCRIS + CPI-U	$2,749,561,756	CY 2019 HCRIS + CPI-U
MA Direct GME	$1,617,557,770	CY 2019 HCRIS + CPI-U	$1,862,798,849	CY 2019 HCRIS + CPI-U
Pool (not to exceed $60 million)	$60,000,000	((Part A DGME/MA DGME) * (NAH Pass-through))	$60,000,000	((Part A DGME/MA DGME) * (NAH Pass-through))
Percent Reduction to MA DGME Payments	3.71%	(Pool/MA direct GME)	3.22%	(Pool/MA direct GME)

We did not propose any changes to the regulations text at 42 CFR 413.87, as our proposal to include the nursing and allied health MA rates in the IPPS rulemaking was consistent with current regulations.

Comment: A commenter requested clarification on the calculation of the direct GME MA percent reduction and questioned if it is separate from the allocation of funds used for the NAH pass-through payment.

Response: We appreciate the commenter's request for clarification. As explained previously in the background section, under sections 541 of the BBRA and 512 of BIPA, hospitals that operate approved nursing or allied health education programs and receive Medicare reasonable cost reimbursement for these programs would receive additional payments for services associated with MA enrollees. Section 541 of the BBRA limits total spending under the provision to no more than $60 million in any calendar year (CY). Section 541 of the BBRA also provides for estimated reductions in direct GME MA payments, which are to equal the estimated total additional MA NAH payments. Thus, nationally, the estimated reductions to direct GME MA payments would not be more than $60 million in any CY. However, on a hospital-specific basis, the direct GME MA percent reduction is not necessarily tied to receipt of the MA NAH add-on payment. That is, hospitals that are both teaching hospitals receiving direct GME payments and that operate approved NAH programs may be affected by both aspects of these laws; such hospitals may receive both a payment for MA NAH, while also receiving a reduced direct GME MA payment. Hospitals that only operate NAH programs may only receive the MA NAH payment; conversely, teaching hospitals with no approved NAH programs would only receive the reduced direct GME MA payment.

We received numerous comments regarding various aspects of the MA NAH add-on and the direct GME MA percent reduction, expressing opposition to reconciliation of overpayments, voicing concerns regarding reimbursement that does not adequately reflect current costs and nursing and healthcare workforce shortages, and opposing reductions to direct GME payments to fund NAH programs. While concerns expressed in these comments may be important, we did not specifically make proposals related to those concerns. These comments are out of scope, and therefore, we are not responding to them at this time.

For this final rule, consistent with the use of HCRIS data for past calendar years, for CY 2020, we use data from cost reports ending in FY 2018 HCRIS (the fiscal year that is 2 years prior to CY 2020) to compile these national amounts: NAH pass-through payment, Part A Inpatient Days, MA Inpatient Days. We use data from cost reports ending in FY 2019 HCRIS (the fiscal year that is 2 years prior to CY 2021) to compile the same national amounts for CY 2021. For this final rule, we accessed the HCRIS data from the first quarterly HCRIS update of 2022. However, to calculate the ''pool'' and the direct GME MA percent reduction, we ''project'' Part A direct GME payments and MA direct GME payments for the current calendar years, which in this final rule, are CYs 2020 and 2021 as the best available cost report data. Next, consistent with the method we described previously from the August 1, 2000 IFC, we increased these payment amounts from midpoint to midpoint of the appropriate calendar year using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME, and the Consumer Price Index–Urban (CPI–U) increases for Part A direct GME. For CY 2020, the direct GME projections are based on FY 2019 HCRIS. For CY 2021, the direct GME projections are based on FY 2019 HCRIS. For CYs 2020 and 2021, the final national rates and percentages, and their data sources are set forth in this table.

	CY 2020	SOURCE	CY 2021	SOURCE
NAH Pass-Through	$ 264,332,386	Cost reports ending in FY 2018 HCRIS	$ 276,790,522	Cost reports ending in FY 2019 HCRIS
Part A Inpatient Days	64,285,989	Cost reports ending in FY 2018 HCRIS	66,512,964	Cost reports ending in FY 2019 HCRIS
MA Inpatient Days	9,473,935	Cost reports ending in FY 2018 HCRIS	10,702,732	Cost reports ending in FY 2019 HCRIS
Part A Direct GME	$ 2,772,451,903	CY 2019 HCRIS + CPI-U	$ 2,732,276,287	CY 2019 HCRIS + CPI-U
MA Direct GME	$1,608,018,609	CY 2019 HCRIS + CPI-U	$ 1,840,934,928	CY 2019 HCRIS + CPI-U
Pool (not to exceed $60 million)	$ 60,000,000	((Part A DGME/MA DGME) * (NAH Pass-through))	$ 60,000,000	((Part A DGME/MA DGME) * (NAH Pass-through))
Percent Reduction to MA DGME Payments	3.71%	(Pool/MA direct GME)	3.22%	(Pool/MA direct GME)

In summary, after consideration of the public comments received, we are finalizing our proposal to use NAH MA add-on rates as well as the direct GME MA percent reductions for CYs 2020 and 2021, based on sufficient HCRIS data to develop the rates for these years. We expect to propose to issue the rates for CY 2022 in the FY 2024 IPPS/LTCH PPS proposed rule, and the rates for CY 2023 in the FY 2025 IPPS/LTCH PPS proposed rule, and so forth.

4. Allowance of Medicare GME Affiliation Agreements Within Certain Rural Track FTE Limitations

Sections 1886(h)(4)(F) and 1886(d)(5)(B)(v) of the Act established limits on the number of allopathic and osteopathic residents that hospitals may count for purposes of calculating direct GME payments and the IME adjustment, respectively, thereby establishing hospital-specific direct GME and IME full-time equivalent (FTE) resident caps. However, under the authority granted by section 1886(h)(4)(H)(ii) of the Act, the Secretary may issue rules to allow institutions that are members of the same affiliated group to apply their direct GME and IME FTE resident caps on an aggregate basis through a Medicare GME affiliation agreement. The Secretary's regulations permit hospitals, through a Medicare GME affiliation agreement, to increase or decrease their IME and direct GME FTE resident caps to reflect the rotation of residents among affiliated hospitals for agreed-upon academic years. Consistent with the broad authority conferred by the statute, we established criteria for defining an ''affiliated group'' and an ''affiliation agreement'' in both the August 29, 1997, final rule (62 FR 45966, 46006) and the May 12, 1998, final rule (63 FR 26318). In the August 1, 2002, IPPS final rule (67 FR 50069), we amended our regulations to require that each Medicare GME affiliation agreement must have a shared rotational arrangement. The term ''Medicare GME affiliation agreement'' is defined at 42 CFR 413.75(b) as a written, signed, and dated agreement by responsible representatives of each respective hospital in a Medicare GME affiliated group, as defined in § 413.75(b), that specifies—

- The term of the Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year;
- Each participating hospital's direct and indirect GME FTE caps in effect prior to the Medicare GME affiliation;
- The total adjustment to each hospital's FTE caps in each year that the Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect FTE caps that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount;
- The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's FTE caps (in accordance with in accordance with paragraph (3) of this definition); and
- The names of the participating hospitals and their Medicare provider numbers.

We also define the term ''Shared Rotational Arrangement'' in that section of our rules as a residency training program under which a resident(s) participates in training at two or more hospitals in that program.

To encourage the training of residents in rural areas, section 407(c) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) (BBRA) amended section 1886(h)(4)(H) of the Act to add a provision (subsection (iv)) stating that, in the case of a hospital that is not located in a rural area (an urban hospital) that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area, or has an accredited training program with an integrated rural track, the Secretary shall adjust the urban hospital's cap on the number of FTE residents under section 1886(h)(4)(F) of the Act, in an appropriate manner in order to encourage training of physicians in rural areas. Historically, the Accreditation Council for Graduate Medical Education (ACGME) has separately accredited family medicine programs in the ''1–2 format'' (meaning, residents in the 1–2 format receive their first year experience at a core family medicine program, and their second and third year experiences at another site, which may or may not be rural). Section 407(c) of Public Law 106–113 was effective for direct GME payments to hospitals for cost reporting periods beginning on or after April 1, 2000, and for IME payments applicable to discharges occurring on or after April 1, 2000. We refer readers to the August 1, 2000, interim final rule with comment period (65 FR 47025, 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39828, 39902 through 39909) where we implemented section 407(c) of Public Law 106–113. The regulations for establishing rural track FTE limitations are located at 42 CFR 413.79(k) for direct GME and at 42 CFR 412.105(f)(1)(x) for IME. (We note that additional legislative and regulatory changes were made to Rural Track Programs in the December 27, 2021 final rule, 86 FR 73445.)

When we first implemented the rural track regulations in the August 1, 2000 IFC, we specified that the caps associated with rural tracks are separate and distinct from a hospital's general FTE caps. Specifically, we defined Rural track FTE limitation at 42 CFR 413.75(b) as the maximum number of residents training in a rural track residency program that an urban hospital may include in its FTE count and that is in

addition to the number of FTE residents already included in the hospital's FTE cap (emphasis added). As a result, the rural track FTE limitations are not part of the regular FTE caps that hospitals may aggregate in Medicare GME affiliation agreements.

The rural track FTE limitations are calculated in the same manner as the adjustments to any allowable new program, in accordance with 42 CFR 413.79(e)(1). That is, at the end of the 5-year cap building window for the rural track program, the urban hospital's and rural hospital respective IME and direct GME rural track FTE limitations are calculated as the product of three factors (limited to the number of accredited slots for each program):

- The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence at all of the hospitals to which the residents in the program rotate.
- The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.
- The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

Thus, while the calculated rural track FTE limitations calculated at the end of the 5-year window may reflect the division of the rotations between the urban and rural hospitals over the 5 initial years of the program, the future rotations amounts may change somewhat (albeit adhering to greater than 50 percent of the duration of the training occurring in the rural hospital/rural area). As rotations shift to meet patient care needs, the respective rural track FTE limitations may not quite match the amount of FTEs actually training in the urban and rural hospitals. There has been request that the same flexibility with cap sharing afforded to teaching hospitals to share general FTE cap slots via Medicare GME affiliation agreements also be afforded to urban and rural teaching hospitals that together train residents in a rural track program. This flexibility would allow the urban and rural hospitals to share their rural track FTE limitations in a manner that best matches the rotations occurring in the urban and rural hospitals. Stakeholders representing urban-rural training partnerships specifically raised this request with regard to separately accredited 1–2 family medicine programs that have existed for a number of years, and either already have established their rural track FTE limitations, or have just recently reached or will reach the end of their 5-year cap building windows.

We have considered this request and agree it would be equitable to allow an urban and rural hospital jointly training residents in a 1–2 separately accredited family medicine program to aggregate their respective IME and direct GME rural track FTE limitations and enter into a ''Rural Track Medicare GME Affiliation Agreement'' to share those cap slots, and facilitate the cross-training of residents. We proposed to allow urban and rural hospitals that participate in the same separately accredited 1–2 family medicine rural track program and have rural track FTE limitations to enter into ''Rural Track Medicare GME Affiliation Agreements.'' We proposed that programs that are not separately accredited in the 1–2 format and are not in family medicine would not be permitted to enter into ''Rural Track Medicare GME Affiliation Agreements'' under this proposal. These Rural Track Medicare GME Affiliation Agreements, which we proposed to define in this final rule, will be structured similarly to regular Medicare GME affiliation agreements, but we proposed two distinct requirements.

First, in an effort to ensure that regular FTE caps and FTE residents in non-rural track programs are not commingled with the rural track FTE residents, and that rural track FTE limitations are not being used to provide additional cap slots for non-rural track FTE residents, we proposed that the responsible representatives of each urban and rural hospital entering into the Rural Track Medicare GME Affiliation Agreement must attest in that written agreement that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program. We noted this attestation is important for both the urban and rural hospital, as both urban and rural hospitals may have regular FTE caps that could be part of regular Medicare GME affiliation agreements (see 42 CFR 413.79(e)(1)(iv) and (v) and 413.79(f)). Second, we proposed to only allow urban and rural hospitals to participate in Rural Track Medicare GME Affiliated Groups if they are separately accredited 1–2 family medicine programs that have rural track FTE limitations in place prior to October 1, 2022. We proposed to choose these criteria and this date of October 1, 2022, as the date by which eligible hospitals must have rural track FTE limitations in place because the effective date of section 127 of the Consolidated Appropriations Act (CAA) is cost reporting periods beginning on or after October 1, 2022, and we proposed to limit this proposal to only rural track FTE limitations established under the BBRA of 1999 that are unaffected by section 127 of the CAA. In this final rule, we are distinguishing between rural track programs with rural track FTE limitations associated with the BBRA of 1999 in effect prior to October 1, 2022, and Rural Track Programs (RTPs, defined at 42 CFR 413.75(b)) started or expanded to new participating sites under the authority of section 127 of the CAA. We explain this distinction later in this section of the final rule.

First, we refer readers to the December 27, 2021, final rule (86 FR 73445) for details about section 127 of the CAA. Generally, that provision removes the requirement that rural track programs be separately accredited, places in statute (previously in regulation) the requirement that rural track residents must spend greater than 50 percent of their training time in a rural area, and allows urban and rural hospitals to receive adjustments to their rural track FTE limitations for adding new rural training sites to an existing rural track program. In that December 27, 2021, final rule, we addressed a comment (86 FR 73456) that requested whether multiple rural hospital training sites added under the new section 127 authority may share their rural track FTE limitations via a Medicare GME affiliation agreement. We responded that effective October 1, 2022, we are not permitting the formation of Medicare GME affiliated groups for the purpose of aggregating and cross-training RTP FTE limitations. First, we explained that we believe Medicare GME affiliated groups for RTPs would be premature, as only starting October 1, 2022, would hospitals have the first opportunity to add additional participating sites. Subsequently, there would be the 5-year cap building period in which Medicare GME affiliations are not permitted, even under existing Medicare GME affiliation agreement rules (42 CFR 413.79(f)). Second, we stated that before we create Medicare GME affiliation agreements unique to RTPs, we believe it would be best to first modify the Medicare cost report form to add spaces for the hospitals to indicate the number of any additional RTP FTEs, and the caps applicable to those FTEs. We also stated that we wish to assess flexibility within a hospital's own total RTP FTE limitation, before sharing those slots with other hospitals. We would need to be vigilant to ensure

that the RTP FTE limitations are not comingled with regular FTE cap adjustments currently used in Medicare GME affiliation agreements. Therefore, we concluded with our belief that it is best to reassess allowing Medicare GME affiliation agreements for RTP FTE limitations at some point in the future. For these same reasons, at this time, we believe it is appropriate to only propose to allow rural track Medicare GME affiliation agreements with urban and rural hospitals that have a rural track FTE limitation in place prior to October 1, 2022. We will assess allowing these agreements with RTP FTE limitations established after October 1, 2022, in the future.

We proposed the following new definitions and requirements at 42 CFR 413.75(b):

• ''Rural track Medicare GME affiliated group'' is an urban hospital and a rural hospital that participates in a rural track program defined in 42 CFR 413.75(b), and that have rural track FTE limitations in effect prior to October 1, 2022, and that comply with 42 CFR 413.79(f)(1) through (6) for Medicare GME affiliated groups.

• ''Rural track Medicare GME affiliation agreement'' is a written, signed, and dated agreement by responsible representatives of each respective hospital in a rural track Medicare GME affiliated group, as defined in 42 CFR 413.75(b), that specifies—

++ A statement attesting that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program.

++ The term of the rural track Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year;

++ Each participating hospital's direct and indirect GME rural track FTE limitations in effect prior to the rural track Medicare GME affiliation;

++ The total adjustment to each hospital's rural track FTE limitations in each year that the rural track Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect rural track FTE limitations that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect rural track FTE limitations of at least the same amount;

++ The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the rural track Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's rural track FTE limitations (in accordance with paragraph (iii) of the definition (regarding the total adjustment to each hospital's rural track FTE limitations previously noted)); and

++ The names of the participating hospitals and their Medicare provider numbers.

In addition, we proposed to require that no later than July 1 of the residency year during which the rural track Medicare GME affiliation agreement will be in effect, the urban and rural hospital must submit the signed agreement to the CMS contractor or MAC servicing the hospital and send a copy to the CMS Central Office. The hospitals may submit amendments to the adjustments to their respective rural track FTE limitations to the MAC with a copy to CMS by June 30 of the residency year that the agreement is in effect. We proposed that eligible urban and rural hospitals may enter into rural track Medicare GME affiliation agreements effective with the July 1, 2023, academic year.

With regard to how the rural track Medicare GME affiliation adjustments would be reported on the Medicare cost report, first, for background, we noted in the proposed rule that on the previous Medicare cost report CMS–Form–2552–96, the rural track FTE limitation was combined, together with the ''cap'' add-on for new (non-rural track) programs on Worksheet E, Part A, line 3.05, and on Worksheet E–3, Part IV, line 3.02. On the current cost report CMS–Form–2552–10, the rural track FTE limitation is, likewise, combined together with the ''cap'' add-on for new (non-rural track) programs on Worksheet E, Part A, line 6, and on Worksheet E–4, line 2. We stated in the proposed rule that going forward, we intend to add lines to the cost report to accommodate separate reporting of urban or rural hospital rural track FTE limitations, and the positive or negative adjustments made to the rural track FTE limitations, including those applicable to the affiliated agreements.

In summary, we proposed to allow urban and rural hospitals that participate in the same separately accredited 1–2 family medicine rural track program and have rural track FTE limitations to enter into ''Rural Track Medicare GME Affiliation Agreements''. We proposed that programs that are not separately accredited in the 1–2 format and are not in family medicine would not be permitted to enter into ''Rural Track Medicare GME Affiliation Agreements'' under this proposal. We proposed to add new definitions at 42 CFR 413.75(b) of rural track Medicare GME affiliated group and rural track Medicare GME affiliation agreement. We also proposed to require that the responsible representatives of each urban and rural hospital entering into the rural track Medicare GME affiliation agreement must attest in that agreement that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program. In addition, we proposed to only allow urban and rural hospitals to participate in rural track Medicare GME affiliated groups if they have rural track FTE limitations in place prior to October 1, 2022. We proposed that eligible urban and rural hospitals may enter into rural track Medicare GME affiliation agreements effective with the July 1, 2023, academic year.

Comment: The majority of commenters strongly supported CMS's proposal to enable rural training flexibilities through Medicare GME affiliation agreements between urban and rural hospitals that have rural track programs. Some commenters ''applauded'' CMS for its attention to rural GME training, and appreciated additional options for cap flexibilities afforded to rural hospitals. A commenter stated that the proposal will assist urban hospitals in providing flexibilities needed to address disparities affected by geography and other social determinants of care. Some commenters stated that the proposal will help provide care to Medicare beneficiaries and may create interest for future physicians to practice in rural settings. Many commenters who supported the proposal also added that CMS should engage in future rulemaking that will allow any RTP, not just those separately accredited in family medicine that were established prior to October 1, 2022, to also engage in affiliation agreements following the conclusion of the cap-building period.

Response: We thank the commenters for their feedback and support. As we stated in the proposed rule, we proposed to only allow urban and rural hospitals to participate in Rural Track Medicare GME Affiliated Groups if they are separately accredited 1–2 family medicine programs that have rural track FTE limitations in place prior to October 1, 2022. We stated that we are distinguishing between rural track programs with rural track FTE

limitations associated with the BBRA of 1999 in effect prior to October 1, 2022, and Rural Track Programs (RTPs, defined at 42 CFR 413.75(b)) started or expanded to new participating sites under the authority of section 127 of the CAA effective on or after October 1, 2022. We explained that we are not permitting the formation of Medicare GME affiliated groups for the purpose of aggregating and cross-training RTP FTE limitations effective on or after October 1, 2022, because we believe Medicare GME affiliated groups for RTPs would be premature, as only starting October 1, 2022, would hospitals have the first opportunity to add additional participating sites. Subsequently, there would be the 5-year cap building period in which Medicare GME affiliations would not be permitted, even under existing Medicare GME affiliation agreement rules (42 CFR 413.79(f)). In addition, we stated that before we created Medicare GME affiliation agreements unique to RTPs, we believe it would be best to first modify the Medicare cost report form to add spaces for the hospitals to indicate the number of any additional RTP FTEs, and the caps applicable to those FTEs. We also stated that we wished to assess flexibility within a hospital's own total RTP FTE limitation, before sharing those slots with other hospitals. We would need to be vigilant to ensure that the RTP FTE limitations were not comingled with regular FTE cap adjustments currently used in Medicare GME affiliation agreements. We concluded with our belief that it would be best to reassess allowing Medicare GME affiliation agreements for RTP FTE limitations at some point in the future. For these same reasons, at this time, we believe it is appropriate to only propose to allow rural track Medicare GME affiliation agreements with urban and rural hospitals that have a separately accredited rural track program and rural track FTE limitation in place prior to October 1, 2022. We will assess allowing these agreements with RTP FTE limitations established after October 1, 2022, in the future.

Comment: A commenter representing a group of organizations opposed CMS's proposal to allow Medicare GME affiliation agreements for rural track programs with FTE limitations prior to October 1, 2022, and did not believe the use of affiliation agreements resolves concerns over the inequity of the current method for determining a cap to be applied to rural track programs. The commenter was concerned that the proposal establishes additional barriers to many programs. The commenter believed that the proposal is too narrow, limited only to family medicine training, and only to separately accredited training tracks established prior to the CAA 2021. Specifically, the commenter observed that currently, CMS counts the time residents spend training at the rural site, across five years, and the time spent in the urban setting, and then counts the highest number (in any program year) during the fifth year of the cap-setting window across all participating hospitals. Because a rural track program typically has its residents train in the urban hospital in year one, rather than in the rural setting, the urban hospital gets more than its fair share of the cap, and the rural site gets less than the actual number of FTEs training in that site. When apportioned this way, rural sites are disadvantaged compared to urban hospital sites. The commenter noted that a mechanism already exists for Medicare affiliated groups to aggregate caps other than ''rural FTE limitations,'' and stated that they ''are aware of multiple occasions where such aggregation has occurred between urban and rural hospitals, always to the disadvantage of the rural hospital that has, for example, been acquired by the larger urban health system. It seems unlikely that urban hospitals would give up ''rural FTE limitation'' slots to benefit a participating rural hospital's cap . . .'' The commenter stated that CMS has the authority to make changes to the calculation of rural cap limitations as section 127 of the CAA states that the Secretary shall ''adjust in an appropriate manner the limitation under subparagraph (F) for such hospital and each such hospital located in a rural area that participates in such a training'' (emphasis added). As such, beginning with cost reporting periods on or after October 1, 2022, CMS is not restricted to only sharing positions through an affiliation agreement but should set appropriate caps associated with these training programs for the future, rather than institute affiliation agreements. This commenter and another commenter recommended that the solution is to count the highest year, rather than using all five years when determining the ratio for cap apportionment.

Response: We appreciate the concerns raised by the commenter and acknowledge the commenter's unique perspective on rural GME training. We certainly want to initiate a payment mechanism that is inherently equitable, and believe that a policy that we finalize should encourage, rather than hinder, GME training in rural areas. However, we note that the vast majority of commenters, including others with close ties to rural GME training, have submitted comments in support of our proposal, generally stating that this proposal will facilitate training in rural settings.

With regard to the commenter's point that CMS's current methodology of looking at all 5 years to apportion FTE caps disadvantages the rural hospital in a RTP because the method gives more than the fair share of FTE cap to the urban hospital, we acknowledge that there might be other mathematical apportionment methods that, if tailor-made for RTPs, would result in higher caps for the rural hospital. However, we note that this current mathematical apportionment in the regulations at 42 CFR 413.79(e)(1) and (3) was first implemented for all hospitals in the August 1, 2012 LTCH PPS/IPPS final rule (77 FR 53416 through 53424). Then in the August 22, 2016 LTCH PPS/IPPS final rule, we adopted this same cap apportionment methodology for rural track FTE limitations (81 FR 57026 through 57031), without any objection from commenters. Thus, we have established a single, national policy for calculating FTE caps for new programs and RTPs, and we have not proposed a change to this national method in the proposed rule. While a ''one-size-fits-all'' method may not be optimal in all situations, we do not believe it is advisable to alter the cap calculation for RTPs at this time. With the advent of CAA section 127, and the expectation that RTPs will develop not only in 3-year family medicine programs, but also in many other specialties of differing lengths, it is not the right time to establish an RTP cap calculation method, before we even understand what the RTP landscape will be like over the next 5 or more years. At this point, allowing Medicare GME affiliation agreements between the urban and rural hospitals participating in the same RTP may be the better solution, as it would allow the hospitals to customize their individual caps, rather than CMS instituting yet another national cap calculation methodology. Furthermore, because the majority of commenters supported our proposal to allow Rural Track Medicare GME Affiliation Agreements, we believe it is fair and appropriate to finalize our policy as proposed. In the December 27, 2021 final rule (86 FR 73456), and as reiterated in the proposed rule and in response to other comments in this final rule, we already stated that we expect to reassess allowing Medicare GME affiliation agreements for RTP FTE

limitations established after October 1, 2022 at some point in the future. For these same reasons, and in conjunction with observing what we hope will be robust growth and development of RTPs in many specialties, not just family medicine, we are open to reassessing at the appropriate time the viability of Rural Track Medicare GME Affiliation Agreements for appropriate payment for urban and rural hospitals participating in RTPs.

Comment: Another commenter who supported our proposal added that they believe CMS's concerns about hospitals taking advantage of affiliated agreements and comingled caps are misguided, and that placing this limitation on affiliated agreements within RTPs is inappropriate. The commenter asserted that urban and rural hospitals participating in any RTP program for the benefit of rural communities should be permitted this flexibility, as it would promote the adoption of the model partnerships.

Response: As we stated in the proposed rule, when we first implemented the rural track regulations in the August 1, 2000 IFC, we specified that the caps associated with rural tracks are separate and distinct from a hospital's general FTE caps. Specifically, we defined the ''rural track FTE limitation'' at 42 CFR 413.75(b) as the maximum number of residents training in a rural track residency program that an urban hospital may include in its FTE count and that is *in addition to the number of FTE residents already included in the hospital's FTE cap* (emphasis added). As a result, the rural track FTE limitations are not part of the regular FTE caps that hospitals may aggregate in Medicare GME affiliation agreements. In the proposed rule, we proposed that the responsible representatives of each urban and rural hospital entering into the Rural Track Medicare GME Affiliation Agreement attest in that written agreement that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program. We noted this attestation is important for both the urban and rural hospital, as both urban and rural hospitals may have regular FTE caps that could be part of regular Medicare GME affiliation agreements (see 42 CFR 413.79(e)(1)(iv) and (v) and 413.79(f)). Accordingly, as long as it is possible for a hospital to have both regular FTE caps and rural track FTE limitations, we believe it is appropriate to have mechanisms in place to ensure those caps are not inadvertently comingled. We do not believe these mechanisms limit the flexibility of rural hospitals seeking to create model partnerships, as the commenter asserts.

Comment: A commenter offered one minor suggestion on language used to describe the programs encompassed in the proposal to allow Medicare GME affiliation agreements within certain rural track FTE limitations. The commenter offered these suggestions in the interest of accurate references to ACGME terminology and processes. The commenter suggested eliminating use of the outdated term ''1–2'' when referring to separately accredited family medicine programs. CMS could instead consider phrasing such as ''separately accredited family medicine programs with caps in place as of October 1, 2022.''

Response: We appreciate the commenter's suggestion, and in this final rule, we are finalizing our policy with respect to ''separately accredited family medicine programs with rural track FTE limitations in place as of October 1, 2022.''

After consideration of the public comments we received, we are finalizing our proposal, without modification, to allow urban and rural hospitals that participate in the same separately accredited family medicine RTP and have rural track FTE limitations to enter into ''Rural Track Medicare GME Affiliation Agreements''.

We are finalizing the following new definitions at 42 CFR 413.75(b) and requirements:

• *Rural track Medicare GME affiliated group* is an urban hospital and a rural hospital that participates in a rural track program defined in 42 CFR 413.75(b), and that have rural track FTE limitations in effect prior to October 1, 2022, and that comply with 42 CFR 413.79(f)(1) through (6) for Medicare GME affiliated groups.

• *Rural track Medicare GME affiliation agreement* is a written, signed, and dated agreement by responsible representatives of each respective hospital in a rural track Medicare GME affiliated group, as defined in 42 CFR 413.75(b), that specifies—

++ A statement attesting that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program.

++ The term of the rural track Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year;

++ Each participating hospital's direct and indirect GME rural track FTE limitations in effect prior to the rural track Medicare GME affiliation;

++ The total adjustment to each hospital's rural track FTE limitations in each year that the rural track Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect rural track FTE limitations that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect rural track FTE limitations of at least the same amount;

++ The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the rural track Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's rural track FTE limitations (in accordance with paragraph (iii)); and

++ The names of the participating hospitals and their Medicare provider numbers.

In addition, we are requiring that no later than July 1 of the residency year during which the rural track Medicare GME affiliation agreement will be in effect, the urban and rural hospital must submit the signed agreement to the CMS contractor or MAC servicing the hospital and send a copy to the CMS Central Office. The hospitals may submit amendments to the adjustments to their respective rural track FTE limitations to the MAC with a copy to CMS by June 30 of the residency year that the agreement is in effect. Eligible urban and rural hospitals may enter into rural track Medicare GME affiliation agreements effective with the July 1, 2023, academic year.

With regard to how the rural track Medicare GME affiliation adjustments would be reported on the Medicare cost report, first, for background, we note that on the previous Medicare cost report CMS–Form–2552–96, the rural track FTE limitation was combined, together with the ''cap'' add-on for new (non-rural track) programs on Worksheet E, Part A, line 3.05, and on Worksheet E–3, Part IV, line 3.02. On the current cost report CMS–Form–2552–10, the rural track FTE limitation is, likewise, combined together with the ''cap'' add-on for new (non-rural track) programs on Worksheet E, Part A, line 6, and on Worksheet E–4, line 2. Going forward, we intend to add lines to the cost report to accommodate separate reporting of urban or rural hospital rural

track FTE limitations, and the positive or negative adjustments made to the rural track FTE limitations, including those applicable to the affiliated agreements.

G. Payment Adjustment for Certain Clinical Trial and Expanded Access Use Immunotherapy Cases (§§ 412.85 and 412.312)

Effective for FY 2021, we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3 (85 FR 58599 through 58600). Effective for FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106). We refer the reader to section II.D.17. of the preamble of this final rule for discussion of the agenda items for the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting relating to new procedure codes to describe the administration of a CAR T-cell or another type of gene or cellular therapy product, as well as our established process for determining the MS–DRG assignment for codes approved at the March meeting.

Effective for FY 2021, we modified our relative weight methodology for MS–DRG 018 in order to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, under our finalized policy we do not include claims determined to be clinical trial claims that group to MS–DRG 018 when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that: (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for MS DRG 018 to the extent such claims can be identified in the historical data; and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). The term ''expanded access'' (sometimes called ''compassionate use'') is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.[215]

Effective FY 2021, we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access immunotherapy cases that group to MS–DRG 018 using the same methodology that we used to adjust the case count for purposes of the relative weight calculations (85 FR 58842 through 58844). (As previously noted, effective beginning FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).) Specifically, under our finalized policy we apply a payment adjustment to claims that group to MS–DRG 018 and include ICD–10–CM diagnosis code Z00.6, with the modification that when the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment will not be applied in calculating the payment for the case. We also finalized that when there is expanded access use of immunotherapy, the payment adjustment will be applied in calculating the payment for the case. This payment adjustment is codified at 42 CFR 412.85 (for operating IPPS payments) and 42 CFR 412.312 (for capital IPPS payments), for claims appropriately containing Z00.6, as described previously, and reflects that the adjustment is also applied for cases involving expanded access use immunotherapy, and that the payment adjustment only applies to applicable clinical trial cases; that is, the adjustment is not applicable to cases where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product. The regulations at 42 CFR 412.85(c) also specify that the adjustment factor will reflect the average cost for cases to be assigned to MS–DRG 018 that involve expanded access use of immunotherapy or are part of an applicable clinical trial to the average cost for cases to be assigned to MS–DRG 018 that do not involve expanded access use of immunotherapy and are not part of a clinical trial (85 FR 58844).

For FY 2023, we proposed to continue to apply an adjustment to the payment amount for expanded access use of immunotherapy and applicable clinical trial cases that would group to MS–DRG 018 using the same methodology adopted in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58842), which is the same methodology we proposed to use to adjust the case count for purposes of the relative weight calculations:

- Calculate the average cost for cases to be assigned to MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for all other cases to be assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for expanded access use of immunotherapy and applicable clinical trial cases that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

Additionally, we proposed to continue to use our finalized methodology for calculating this payment adjustment, such that: (a) when the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases; and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases. However, we continue to believe to the best of our knowledge there are no claims in the historical data (FY 2021 MedPAR) used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000. We note that we are in the process of making modifications to the MedPAR files to include information for claims with the payer-only condition code ''ZC'' in the future. Payer-only condition code ''ZC'' is used by the IPPS Pricer to identify a case where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product so that the payment adjustment is not applied in calculating the payment for the case (for example, see Change Request 11879, available at *https://www.cms.gov/files/document/r10571cp.pdf*).

[215] *https://www.fda.gov/news-events/expanded-access/expanded-access-keywords-definitions-and-resources.*

Consistent with our calculation of the proposed adjustor for the relative weight calculations, and our proposal to use the FY 2021 data for the FY 2023 ratesetting, for the proposed rule we proposed to calculate this adjustor based on the December 2021 update of the FY 2021 MedPAR file for purposes of establishing the FY 2023 payment amount. Specifically, in accordance with 42 CFR 412.85 (for operating IPPS payments) and 42 CFR 412.312 (for capital IPPS payments), we proposed to multiply the FY 2023 relative weight for MS–DRG 018 by a proposed adjustor of 0.20 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018, which includes CAR T-cell and non-CAR T-cell therapies and other immunotherapies. We also proposed to update the value of the adjustor based on more recent data for the final rule.

We note that a commenter requested that CMS consider allowing hospitals to use expanded access condition code 90 instead of the remarks field, which would remove a layer of manual work required by the MACs, which would decrease the opportunity for errors. As discussed more fully in our response to this comment in section II.E.2.b. of this final rule, we agree with the commenter's request, and effective October 1, 2022, providers should submit condition code 90 to identify expanded access claims that group to MS–DRG 018, rather than the remarks field. We did not receive any comments specifically relating to the proposed payment adjustment for applicable clinical trial and expanded access use immunotherapy cases.

After consideration of the comment we received, we are finalizing our proposal regarding the calculation of this payment adjustment for FY 2023, as described previously. We are also finalizing our proposal to update the value of this adjustor based on more recent data for this final rule. Therefore, using the March 2022 update of the FY 2021 MedPAR data, we are finalizing an adjustor of 0.21 for FY 2023, which will be multiplied by the final FY 2023 relative weight for MS–DRG 018 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018.

H. Hospital Readmissions Reduction Program: Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, establishes the Hospital Readmissions Reduction Program. Under the Hospital Readmissions Reduction Program, Medicare payments under the acute inpatient prospective payment system (IPPS) for discharges from an applicable hospital, as defined under section 1886(d) of the Act, may be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare hospitals with respect to the proportion of beneficiaries who are dually eligible for Medicare and full-benefit Medicaid (also known as ''dually eligible beneficiaries'') in determining the extent of excess readmissions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a detailed discussion of and additional information on the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

We refer readers to the following final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program:

- FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676).
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401).
- FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676).
- FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048).
- FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543).
- FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979).
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240).
- FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439).
- FY 2020 IPPS/LTCH PPS final rule (84 FR 42380 through 42390).
- FY 2021 IPPS/LTCH PPS final rule (85 FR 58844 through 58847.
- FY 2022 IPPS/LTCH PPS final rule (86 FR 45249 through 45266).

We have also codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154.

3. Current Measures

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: Acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery.

We continue to believe the measures we have adopted adequately meet the goals of the Hospital Readmissions Reduction Program. In the FY 2022 IPPS/LTCH PPS final rule, we finalized suppression of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for purposes of payment adjustment for the FY 2023 program year due to the impact of the COVID–19 PHE (86 FR 45254 through 45256). In this final rule, we are finalizing resumption of use of this measure in the Hospital Readmissions Reduction Program beginning with the FY 2024 program year, with an exclusion of patients with principal or secondary COVID–19 diagnoses from both the denominator (cohort) and the numerator (outcome). We are also providing information on technical specification updates for all of the condition/procedure-specific readmission measures in the Hospital Readmissions Reduction Program to include a covariate adjustment for patients with a clinical history of COVID–19 in the 12 months prior to the index admission.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439) for more information about how the Hospital Readmissions Reduction Program supports CMS' goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Framework.

4. Flexibility for Changes That Affect Quality Measures During a Performance Period in the Hospital Readmissions Reduction Program

In the FY 2022 IPPS/LTCH PPS final rule, we adopted a policy for the duration of the COVID–19 PHE that has allowed us to suppress the use of quality measures via adjustment to the Hospital Readmissions Reduction Program's program calculations if we determine that circumstances caused by the COVID–19 PHE significantly affected those measures and the associated ''excess readmissions'' calculations (86 FR 45250 through 45253). As described under that finalized policy, if we were to determine

that the suppression of a Hospital Readmissions Reduction Program measure was warranted for an applicable period, we would calculate the measure's rates for that program year but then suppress the use of those rates to make changes to hospitals' Medicare payments. In the Hospital Readmissions Reduction Program, this policy would have the effect of temporarily weighting the affected measure at zero percent in the program's scoring methodology until adjustments were made, the affected portion of the performance period for the measure was made no longer applicable to program calculations, or the measure was removed entirely through rulemaking. We also explained that we would provide feedback reports to hospitals as part of program activities, including to inform their quality improvement activities, and to ensure that they were made aware of the changes in performance rates that we observed (86 FR 45251). We stated that we would publicly report a suppressed measure's data with appropriate caveats noting the limitations of the data due to the COVID–19 PHE (86 FR 45251). To provide stakeholders an opportunity to review this final rule prior to release of the Hospital Specific Reports (HSRs) that incorporate updates to the CMS 30-Day Pneumonia Readmission Measure (NQF #0506), we are postponing incorporation of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506), which would typically be included in the July update of the Compare website hosted by HHS (*https://www.medicare.gov/care-compare/*).

In the FY 2022 IPPS/LTCH PPS final rule, we also adopted Measure Suppression Factors to guide our determination of whether to suppress a Hospital Readmissions Reduction Program measure for one or more program years that include discharges during the COVID–19 PHE (86 FR 45251). We adopted these Measure Suppression Factors for use in the Hospital Readmissions Reduction Program, and for consistency, the following other value-based purchasing programs: Hospital Value-Based Purchasing, HAC Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and End-Stage Renal Disease Quality Incentive Program. We stated our belief that these Measure Suppression Factors will help us evaluate the Hospital Readmissions Reduction Program's measures and that their adoption in the other value-based purchasing programs, as previously noted, would help ensure consistency in our measure evaluations across programs. The previously adopted Measure Suppression Factors are as follows:

- Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.
- Rapid or unprecedented changes in—

++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

++ The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

- Significant national shortages or rapid or unprecedented changes in—

++ Healthcare personnel;

++ Medical supplies, equipment, or diagnostic tools or materials; or

++ Patient case volumes or facility-level case mix.

We stated our belief that we view this measure suppression policy as necessary to ensure that the Hospital Readmissions Reduction Program did not penalize hospitals based on factors that the program's measures were not designed to accommodate (86 FR 45252).

In the FY 2023 IPPS/LTCH PPS proposed rule, we did not propose any changes to this policy. We did not receive any comments on our previously finalized flexibilities in response to the COVID–19 PHE or our previously finalized Measure Suppression Factors.

5. Provisions That Address the Impact of COVID–19 on Current Hospital Readmissions Reduction Program Measures

a. Background

As described in V.H.4 of the preamble of this final rule, in the FY 2022 IPPS/LTCH PPS final rule, we adopted a measure suppression policy and Measure Suppression Factors to ensure that the Hospital Readmissions Reduction Program did not penalize hospitals based on factors that the program's measures were not designed to accommodate (86 FR 45252).

Additionally, in the FY 2022 IPPS/LTCH PPS final rule, we finalized suppression of the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506) for the FY 2023 program year (86 FR 45254 through 45256). We expressed the belief that the second Measure Suppression Factor (clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID–19 PHE) applied to the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506). In our analysis of the impacts of the COVID–19 PHE on the measures in the Hospital Readmissions Reduction Program, we observed that pneumonia has been identified as a typical characteristic of individuals infected with COVID–19 (86 FR 45254). Using data available during and subsequent to the preparation of the FY 2022 IPPS/LTCH PPS final rule, we found that a substantial portion of the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506) denominator (cohort) included admissions with a COVID–19 diagnosis, ranging from 13.3 percent in April 2020 to a high of 27.1 percent in December 2020.[216] Furthermore, we noted that at the beginning of the pandemic, the 30-day observed readmission rate for pneumonia patients with a secondary diagnosis of COVID–19 present on admission was lower than the observed readmissions rate for pneumonia patients without a diagnosis of COVID–19 (12.4 percent versus 15.8 percent) because patients with a secondary diagnosis of COVID–19 present on admission had a higher risk of mortality than patients without a COVID–19 diagnosis (86 FR 45254 through 45255).

Additionally, we provided information on technical specification updates for the remaining five condition/procedure-specific readmission measures to exclude patients with a principal or secondary COVID–19 diagnosis present on admission from the measures' numerators (outcomes) and denominators (cohorts) beginning in fiscal year (FY) 2023 (86 FR 45256 through 45258). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications adopted for the Hospital Readmissions Reduction Program (79 FR 50039). In the FY 2022 IPPS/LTCH PPS final rule, we noted that to continue to account for readmissions as intended, we would use our subregulatory process to update the specifications to exclude patients with a principal or secondary diagnosis of

[216] While data prior to April 1, 2020 are available, these data used a different method to identify COVID–19 diagnoses. To improve consistency of analysis we began our analysis on April 1, 2020 with the introduction of the COVID–19 ICD–10 codes.

COVID–19 present on admission from the denominators (cohorts) and the numerators (outcomes) of the following five condition/procedure-specific readmission measures: (1) Hospital 30-Day All-Cause RSRR Following AMI Hospitalization (NQF #0505); (2) the Hospital 30-Day, All-Cause, Unplanned, RSRR Following CABG Surgery (NQF #2515); (3) the Hospital 30-Day, All-Cause, RSRR Following COPD Hospitalization (NQF #1891); (4) the Hospital 30-Day, All-Cause RSRR Following Heart Failure Hospitalization (NQF #0330); and (5) the Hospital-Level 30-Day, RSRR Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) beginning in FY 2023 (86 FR 45256).

In the FY 2023 IPPS/LTCH PPS proposed rule, we did not propose any changes to these policies.

b. Resumption of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2024 Program Year

Our measure suppression policy, described in section V.H.4 of the preamble of this final rule, focuses on a short-term, equitable approach during this unprecedented PHE, and was not intended for indefinite application. While we recognize that performance on some measures may not immediately return to levels seen prior to the PHE, we want to emphasize the long-term importance of value-based care and incentivizing quality care by linking provider performance to program payment. The Hospital Readmissions Reduction Program is an example of our long-standing effort to link payments to healthcare quality in the inpatient hospital setting as well as cross-continuum care. Our goal has been to resume the use of measure data for scoring and payment adjustment purposes. We note that in the FY 2022 IPPS/LTCH PPS final rule, we finalized the suppression of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 Program Year and stated that we would continue to monitor the claims that form the basis for this measure's calculations to evaluate the effect of the circumstances on quality measurement and to determine the appropriate policies for the future. Additionally, we recognized that it is important to continue tracking the impact of the COVID–19 PHE on the CMS 30-Day Pneumonia Readmission Measure (NQF #0506), as these data will inform our considerations regarding whether future measure suppression is necessary beyond FY 2023. We noted that the measure is important to improving patient safety and quality of care and stated that we would continue to monitor measure data to determine when it may be considered sufficiently reliable such that resuming full implementation of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) is appropriate (86 FR 45256).

Following publication of the FY 2022 IPPS/LTCH PPS final rule, we have continued to monitor the claims that form the basis for this measure's calculations. While pneumonia continues to be a typical characteristic of individuals infected with COVID–19, we believe that coding practices enhanced by the availability of COVID–19–related ICD–10–CM and ICD–10–PCS codes, effective since January 1, 2021, have enabled us to differentiate patients with COVID–19 from pneumonia patients without COVID–19 within certain data periods.

In this final rule, we are finalizing that beginning in FY 2024, the Pneumonia Readmission Measure (NQF #0506) will no longer be suppressed under the Hospital Readmissions Reduction Program. We will resume the use of the pneumonia readmission measure for FY 2024 because of the following differences between the FY 2023 and FY 2024 performance periods: (1) the improved coding practices; (2) decreased proportion of COVID–19 admissions in the pneumonia readmission measure for this performance period; and (3) sufficient available data to make technical updates to the measure specifications in order to further account for how patients with a COVID–19 diagnosis might impact the quality of care assessed by this measure. These differences lead us to believe that the clinical proximity of the measure's focus is no longer sufficiently close to the health impacts of the COVID–19 PHE for the suppression factor to continue to apply. Specifically, effective January 2021, the ICD–10 code J12.82, pneumonia due to coronavirus disease 2019, was added for use as a secondary diagnosis present on admission, along with a principal diagnosis of COVID–19 (U07.1) present on admission, to identify patients with COVID–19 pneumonia. J12.82 is not included within the denominator (cohort) of the pneumonia readmission measure, therefore readmission rates for patients with an index admission of COVID–19 pneumonia (J12.82) are not captured by this measure as of January 1, 2021. Whenever new codes are introduced, changes in coding practices are difficult to predict. At the time of the FY 2022 IPPS final rule, we did not have sufficient data to determine the effects of these coding changes on the proportion of COVID–19 patients and readmission rates with pneumonia due to COVID–19 in the pneumonia readmission measure. As additional months of data have become available since early 2021, we have now seen increased use of these codes. Secondly, as these coding changes have occurred and as the COVID–19 PHE has evolved, more recent data show the proportion of COVID–19 admissions in the pneumonia readmission measure have decreased compared to 2020 data. Finally, with the availability of additional data and the decrease in the proportion of COVID–19 admissions in the pneumonia readmission measure, we are now able to make technical updates to the measure specifications in alignment with the technical updates to the five other readmission measures. All of these factors have led us to conclude that the suppression factor no longer applies to the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506) measure.

As previously discussed, we observed that in 2020, following the declaration of the COVID–19 PHE for COVID–19 a substantial proportion of the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506) denominator (cohort) included admissions with a COVID–19 diagnosis present on admission. Specifically, the proportion ranged from 13.3 percent when the COVID–19 ICD–10 diagnosis code became available in April 2020 to a high of 27.1 percent in December 2020. After the J12.82 code was implemented in January 2021, the proportion of patients with COVID–19 diagnosis present on admission in the pneumonia measure dropped to 9.8 percent. Data on the proportion of patients with COVID–19 diagnosis present on admission from April 2020 through December 2020 are detailed in Table V.H.-01. The most recently available data at the time of the proposed rule on the proportion of patients with COVID–19 diagnosis present on admission for January through September 2021, which do not include patients with pneumonia due to coronavirus disease 2019 per ICD–10 code J12.82, are detailed in Table V.H–02.

TABLE V.H.-01: PERCENT OF PRINCIPAL OR SECONDARY COVID-19 DIAGNOSES IN READMISSION MEASURE COHORTS APRIL 2020 – DECEMBER 2020

Measure Cohort	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020	October 2020	November 2020	December 2020
Pneumonia	13.3%	11.2%	6.7%	15.6%	14.5%	7.5%	9.5%	17.9%	27.1%
COPD	0.3%	0.2%	0.2%	0.4%	0.5%	0.4%	0.4%	0.9%	1.4%
AMI	0.5%	0.6%	0.5%	1.0%	1.1%	0.8%	0.9%	2.2%	3.6%
HF	0.4%	0.6%	0.6%	0.7%	0.8%	0.6%	0.7%	1.3%	2.1%
THA/TKA	0.3%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.3%	0.5%
CABG	0.1%	0.2%	0.2%	0.4%	0.4%	0.3%	0.3%	0.5%	1.5%

TABLE V.H.-02: PERCENT OF PRINCIPAL OR SECONDARY COVID-19 DIAGNOSES IN READMISSION MEASURE COHORTS JANUARY 2021 – SEPTEMBER 2021

Measure Cohort	January 2021	February 2021	March 2021	April 2021	May 2021	June 2021	July 2021	August 2021	September 2021
Pneumonia	9.8%	5.6%	2.5%	1.9%	1.2%	0.8%	0.7%	2.1%	3.5%
COPD	1.4%	0.9%	0.5%	0.3%	0.3%	0.2%	0.2%	0.6%	0.7%
AMI	3.7%	2.3%	1.2%	0.8%	0.6%	0.4%	0.3%	1.4%	2.0%
HF	2.4%	1.8%	1.0%	0.7%	0.6%	0.3%	0.3%	0.9%	1.1%
THA/TKA	0.6%	0.4%	0.2%	0.2%	0.1%	0.1%	0.1%	0.2%	0.2%
CABG	1.4%	1.1%	0.5%	0.4%	0.3%	0.2%	0.1%	0.5%	0.6%

We note that the surge of COVID–19–related hospitalizations had begun to subside with the rollout of the U.S. vaccination program in early 2021, although hospitalizations began increasing again during late summer 2021 with the COVID–19 Delta variant and increased over the fall and winter with the COVID–19 Omicron variant. We also note that updated data show that the proportion of admissions with a COVID–19 diagnosis present on admission for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) between April 2020 and December 2020 was 13.1 percent, whereas the proportion between January 2021 and September 2021 was substantially lower, at 3.1 percent.

Analyzing data available for the FY 2022 IPPS/LTCH PPS final rule (April 2020 through June 2020), we noted that the 30-day observed readmissions rate for patients with a secondary diagnosis of COVID–19 present on admission at the index admission were lower than the observed readmissions rates for patients without a diagnosis of COVID–19 (12.4 percent versus 15.8 percent). In more recent data, we have found that the observed readmission rate for admissions with a COVID–19 diagnosis present on admission were similar to observed readmission rates for admissions without a COVID–19 diagnosis (17.3 percent vs. 17.2 percent, respectively) as depicted in Table V.H.–03.

TABLE V.H.-03: OBSERVED READMISSION RATE FOR ADMISSIONS WITH/WITHOUT SECONDARY DIAGNOSIS OF COVID-19 PRESENT ON ADMISSION*

	Number of Admissions	Number of Readmissions	Observed 30-Day Readmission Rate
Admissions with Secondary Diagnosis of COVID-19 present on admission	22,967	3,972	17.3%
Admissions without a Diagnosis of COVID-19	757,517	130,067	17.2%

*For the Pneumonia Readmission measure, based on data from July 1, 2018-February 28, 2021, excluding admissions from December 2, 2019-June 30, 2020 reflecting application of the nationwide ECE in response to the COVID-19 ECE.

Because updated data show that following the January 2021 coding update patients with a diagnosis of COVID–19 now make up a smaller proportion of the population of pneumonia admissions than in the analysis described in the FY 2022 IPPS/LTCH PPS final rule, and because observed 30-day readmission rates are

similar between admissions for patients with a COVID–19 diagnosis present on admission and patients without a COVID–19 diagnosis present on admission, we believe that resuming the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) with a modification to exclude patients with a primary or secondary diagnosis of COVID–19 present on admission beginning with the FY 2024 program year would be appropriate. As described in more detail in section V.H.5.c of the preamble of this final rule, we will also add a covariate to adjust for history of COVID–19 diagnosis in the 12 months prior to the index admission as a technical update to the measure specifications.

In our analysis, measure scores calculated with the numerator (outcome) and denominator (cohort) exclusions and addition of the covariate for history of COVID–19 diagnosis in the 12 months prior resulted in mean measure scores that were closer to the prior non-COVID–19 affected period compared with the unchanged measure. We note that these measure-specific modifications are in addition to application of the nationwide ECE granted in response to the COVID–19 PHE, which precludes the use of data from January 1, 2020 through June 30, 2020 from measure score calculations. Because these updates are to minimize the effect of COVID–19 on the pneumonia measure, which was not developed to account for COVID–19 diagnosed patients, we believe that these changes do not fundamentally change the measure such that it is no longer the same measure that we originally adopted, and therefore we believe that these are non-substantive updates. We note that in the FY 2015 IPPS/LTCH PPS final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital Readmissions Reduction Program (79 FR 50039). We reiterated this policy in the FY 2020 IPPS/LTCH PPS final rule, stating our continued belief that the subregulatory process is the most expeditious manner possible to ensure that quality measures remain fully up to date while preserving the public's ability to comment on updates that so fundamentally change a measure that it is no longer the same measure that we originally adopted (84 FR 42385). We believe that excluding COVID–19 patients from the measure denominator (cohort) and numerator (outcome) and adding a covariate to adjust for history of a COVID–19 diagnosis in the 12 months prior to an admission (discussed in section V.H.5.c. of the preamble of this final rule), will ensure that this condition-specific readmission measure continues to account for readmissions as intended and meets the goals of incentivizing patient safety and better care coordination of the Hospital Readmissions Reduction Program. We note that the readmission measure uses three years of data. The performance period for the FY 2023 program year includes admissions from July 1, 2018 through June 30, 2021, with data from January 1, 2020 through June 30, 2020 excluded due to the implementation of the nationwide ECE waiver. Therefore, we continue to believe it is appropriate to suppress the currently implemented measure for use in payment reduction calculations [217] for FY 2023 as finalized in the FY 2022 IPPS/LTCH PPS final rule.

Additional resources about the current measure technical specifications and methodology for the hospital technical specification of the current readmission measures are provided at our website in the Measure Methodology Reports (posted on the QualityNet website at *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*). Hospital Readmissions Reduction Program resources are located at the Resources web page of the QualityNet website (available at *https://qualitynet.cms.gov/inpatient/hrrp/resources*).

We welcomed public comment on our proposal to resume use of the CMS 30-Day Pneumonia Readmissions Measure (NQF #0506) beginning with the FY 2024 program year. The comments we received, and our responses are set forth in this section of this rule.

Comment: Several commenters supported suppressing the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) from the Hospital Readmissions Reduction Program for the FY 2023 program year.

Response: We thank these commenters for their support.

Comment: A few commenters recommended that in addition to suppressing the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) data from payment adjustments for FY 2023, CMS should also suppress these data from public reporting to avoid presenting information that could potentially confuse consumers regarding the quality of care. Some of these commenters noted their continued support for hospital-specific confidential reporting. A commenter recommended that CMS calculate measure information both with and without the exclusion for patients with a diagnosis of COVID–19 present on admission and provide the measure results from both calculations in hospital-specific reports.

Response: We understand the commenters' concern about publicly reporting measure data from the COVID–19 PHE. However, we will make clear in the public presentation of the data that the measure has been suppressed for FY 2023 for purposes of payment adjustments because of the effects of the COVID–19 PHE. We believe that displaying this information will promote transparency on the impacts of the PHE due to COVID–19, and we will appropriately caveat the data in order to mitigate public confusion. Additionally, the Hospital Readmissions Reduction Program Hospital-Specific Report that is sent to hospitals provides discharge-level data for each condition/procedure. The discharge-level data shows whether, and why, a stay was excluded from the numerator (outcome) or denominator (cohort), including stays that are excluded due to a qualifying COVID–19 diagnosis.

Comment: Some commenters recommended that CMS continue reporting all measure results, regardless of whether the measure was being included in program calculations because these commenters believe this supports transparency and accountability. Some of these commenters specifically recommended public and confidential reporting.

Response: We agree with commenters that public reporting of measure results, regardless of whether the measure results were used for payment adjustments, supports transparency and accountability. Therefore, we will continue to report all data with appropriate caveats for the measure results impacted by the COVID–19 PHE. We will also continue to confidentially report these data to hospitals prior to publicly reporting in accordance with our review and correction process detailed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53401).

Comment: Several commenters recommended suppressing the Hospital-Level 30-Day, RSRR Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) measure from payment calculations due to the higher complexity, higher acuity patient population undergoing these procedures

[217] We note that in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28421) this referred to ''payment calculations,'' for accuracy we have revised that here to read ''payment reduction calculations'' as payments are not calculated by the Hospital Readmissions Reduction Program.

on an inpatient basis during the COVID–19 PHE.

Response: We acknowledge that the COVID–19 PHE has impacted the healthcare system in unprecedented ways. However, our analyses of available data to date have found only minimal impacts of COVID–19 on the Hospital-Level 30-Day RSRR Following Elective Primary THA/TKA (NQF #1551) measure results. Furthermore, we believe that the COVID–19 exclusions we have adopted combined with the covariate adjustment for patient history of COVID–19 within 12 months prior to admission described in Section V.H.5.c of this final rule account for the impacts of COVID–19 diagnosed patients. Our analyses have shown that for the FY 2023 program year (that is July 1, 2018 through June 30, 2021 with January 1, 2020 through June 30, 2020 data excluded as a result of implementing the nationwide ECE due to the COVID–19 PHE) reporting results using the updated measure generate very similar measure score distributions compared with FY 2022 program year (that is July 1, 2017 through December 1, 2019) reporting results of the original measure. Additionally, we note that the existing clinical risk adjustments for this measure (available in the Measures Methodology Report at *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*) are designed to account for the complexity and acuity of the patient population. Finally, we believe that hospitals which perform fewer of these procedures due to the shift to outpatient settings may no longer meet the 25-case threshold for inclusion of the measure in the Hospital Readmissions Reduction Program. We will, however, continue to monitor the volume of index admissions for the conditions and procedures that the Hospital Readmissions Reduction Program measures address to ensure that the measures remain appropriate.

Comment: Many commenters supported resuming use of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) in the Hospital Readmissions Reduction Program. Some of these commenters observed that publishing hospital quality data allows trending over time and that public information is vital for consumers.

Response: We thank commenters for their support.

Comment: Several commenters who supported resuming use of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) recommended monitoring to evaluate additional effects of COVID–19 on providers and patients. One of these commenters stated that there may be significant changes in Hospital Readmissions Reduction Program penalties for individual providers because of the effects of COVID–19.

Response: We agree with commenters that we should monitor the COVID–19 PHE's ongoing effects carefully and we will work with measure developers to refine measure specifications as circumstances warrant. We will also assess performance periods, performance, and other effects of the COVID–19 PHE carefully, and we will monitor the policy's effects as we implement it.

Comment: Many commenters recommended postponing resumption of the CMS–30 Day Pneumonia Readmission Measure (NQF #0506). Some of these commenters suggested postponing finalization of our proposal to resume use of the pneumonia readmission measure until the FY 2024 IPPS/LTCH PPS rule to provide at least a full year of use of the new ICD–10 codes. A few commenters recommended postponing resumption until the performance period does not include time prior to the adoption of the new ICD–10 codes, specifically until the performance period does not include any dates prior to January 1, 2021. Other commenters recommended postponing resumption until the COVID–19 PHE has ended because many patients have delayed care, resulting in higher acuity when they received care, which affects the case mix.

Response: We recognize that the COVID–19 PHE continues to affect communities and healthcare systems and understand commenters' concerns that data used in the analysis for the proposed rule may not be representative of the prevalence of COVID–19 and associated changes to admissions patterns after September 2021. However, we believe that the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) is an important aspect of our goal to improve patient safety and quality of care and wish to resume the use of this measure in the Hospital Readmissions Reduction Program at the earliest point that allows for a valid and comparable measure. Based on our analysis of data from the start of the PHE through September 2021, we believe that the measure will be valid and comparable beginning with the FY 2024 program year.

More recent data through March 2022 show that across all Hospital Readmissions Reduction Program measures, less than 3 percent of the cohorts have a COVID–19 diagnosis. Commenters are correct that the FY 2024 program year does include six months after the declaration of the PHE for COVID–19 prior to the adoption of the new ICD–10 codes for COVID–19 (specifically July 1, 2020 through December 31, 2020). However, in our analysis, measure scores calculated based on data which include this period using the numerator (outcome) and denominator (cohort) exclusions and addition of the covariate for history of COVID–19 diagnosis in the 12 months prior to the index admission resulted in mean measure scores that were closer to the prior non-COVID–19 affected period compared with the unchanged measure. Therefore, we believe that the measure is sufficiently valid and comparable to resume use in the FY 2024 program year, despite the six months of data not affected by updated coding practices. Additionally, we note that the existing clinical risk adjustments for this measure (available in the Measures Methodology Report at *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*) are designed to account for the complexity and acuity of the patient population. Because it is our goal to make hospitals aware of our intent to resume use of the measure as early as feasible, we do not believe it would be appropriate to wait until the FY 2024 IPPS/LTCH PPS final rule to finalize resumption of this measure.

After consideration of the public comments we received, we are finalizing our proposal to resume use of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for payment adjustments beginning with the FY 2024 program year.

c. Technical Measure Specification Update To Include a Covariate Adjustment for COVID–19 Beginning with FY 2023

As discussed in section V.H.5.b of the preamble of this final rule, we have previously finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital Readmissions Reduction Program (79 FR 50039) and reiterated this policy in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42385) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45256). As we continue to evaluate the effects of the COVID–19 PHE on our programs, and the effects of COVID–19 on our measures, we have observed that for some patients COVID–19 continues to have lasting effects, including fatigue, cough, palpitations, and others potentially related to organ damage, post-viral syndrome, post-critical care syndrome or other reasons.[218] These clinical conditions

[218] Raveendran, A.V., Jayadevan, R. and Sashidharan, S., *Long COVID: An overview.*

could affect a patient's risk factors for being readmitted following an index admission for any of the six conditions/procedures included in the Hospital Readmissions Reduction Program. Therefore, we are modifying the technical measure specifications of each of our six condition/procedure specific risk-standardized readmission measures to include a covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission beginning with the FY 2023 program year. This inclusion of the covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission will be effective beginning with the FY 2023 program year and for subsequent years for the five non-pneumonia condition- and procedure-specific readmission measures. As described in V.H.5.b, the pneumonia readmission measure remains suppressed from scoring and payment adjustments for the FY 2023 program year and will be resumed for the FY 2024 program year. However, this update will be reflected in the confidential and public reporting of the pneumonia readmission measure for FY 2023.[219] For more information on the application of covariate adjustments, please see the Measure Methodology Reports (posted on the QualityNet website at *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*).

Although we did not solicit comments on the technical measure specification updates to apply a covariate adjustment for patients with a history of COVID–19 in the 12 months prior to the index hospitalization, we received several comments and have summarized them here. We have also included the comments on our technical measure specification update to exclude COVID–19 patients from the measure denominator (cohort) and numerator (outcome) for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) here.

Comment: Many commenters supported both the technical update to adopt a covariate adjustment for patients who have had COVID–19 in the 12 months prior to the index admission for each of the six condition/procedure specific readmission measures in the Hospital Readmissions Reduction Program and the technical update to exclude patients with a COVID–19 diagnosis present on admission from the numerator (outcome) and denominator (cohort) of the pneumonia readmission measure.

Response: We thank these commenters for their support.

Comment: Many commenters expressed concern that many patients with a history of COVID–19 would not be captured in ICD–10–CM codes, specifically mentioning the possibility of these patients being diagnosed through at-home or pharmacy-based tests and then receiving care in visits billed with other codes for resulting conditions. These commenters noted that a covariate adjustment based on data that are inconsistently captured could impact the reliability and validity of the measure results and therefore the fairness of the program. Some of these commenters recommended review by a Technical Expert Panel (TEP) convened by the NQF to ensure that COVID–19 adjustments are sufficiently comprehensive and include all appropriate codes. Some commenters recommended further data analysis to ensure appropriate data sources are available for this adjustment.

Response: We understand the commenters' concerns regarding the prevalence of at-home or pharmacy-based testing for COVID–19 and the potential effects on the validity of the covariate adjustment. The history of COVID–19 variable [220] is defined as U07.1 (COVID–19) or Z86.16 (personal history of COVID–19) in the 12 months prior to the admission, or Z86.16 at the index admission. Therefore, the history of COVID–19 variable does not rely solely on the COVID–10 specific ICD–10 code, U07.1, but also includes the ''personal history of COVID–19'' code (Z86.16) which hospitals can code, even during the index encounter. However, we will consider these concerns and recommendations as we continue to evaluate and update our measure specifications, especially with respect to the ongoing changes to the COVID–19 PHE. We thank commenters for their suggestion of having a special NQF convened TEP review the covariate adjustment methodology to ensure that the adjustments are comprehensive enough to capture the long-term impacts of COVID–19. Any permanent changes to the measure will be submitted for NQF review during the endorsement maintenance process.

Comment: Many commenters observed that the extended effects of COVID–19 on patients are still not known. These commenters recommended continued monitoring to ensure that the 12-month period is appropriate for the covariate adjustment. A commenter recommended adopting a 24-month period as opposed to a 12-month period. A commenter expressed that the effects of the pandemic changing over time may decrease the ability to identify appropriate adjustments, including both the covariate adjustment for patients with a history of COVID–19 in the 12 months prior to index admission and the update to the CMS 30-Day Pneumonia Readmission Measure to exclude patients who have a diagnosis of COVID–19 present at admission from the numerator (outcome) and denominator (cohort). A commenter observed that COVID–19 will likely become an endemic disease. A commenter recommended analyzing cohort-specific risk adjustment and analyses for the COVID–19 patient population due to differences in utilization, infection risk, and readmission risk among these patients.

Response: We thank these commenters for the recommendations. We agree that the extended effects of COVID–19 on patients are still not known. We will consider these recommendations as we continue to evaluate and update our measure specifications, especially with respect to the ongoing changes to the COVID–19 PHE. We note, however, that hospitals can use the ''personal history of COVID'' code (Z86.16) on the index admission which is not affected by a look-back period. We also note that patients who are admitted with a diagnosis of COVID–19 present on admission are excluded from all measures within the Hospital Readmissions Reduction Program. We will continue to monitor and analyze the appropriateness of this exclusion using available data.

Comment: A commenter observed that the measure methodology reports published on CMS's website in May 2022 demonstrate that history of COVID–19 is negatively correlated to readmissions (that is, patients with history of COVID–19 are less likely to be readmitted) for four out of the of five conditions analyzed and recommended to only include the covariate adjustment for conditions where patient history of COVID–19 is a positive risk variable

Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8056514/*. Accessed on December 15, 2021.

[219] We note that the pneumonia readmission measure would typically be included in the July update of the Compare website. However, to provide stakeholders an opportunity to provide comment on these updates, we are postponing incorporation of the pneumonia readmission measure to the January 2023 refresh of the Compare website. (In the proposed rule we stated that the pneumonia measure would be included in the October refresh, however we are correcting that here to the January 2023 refresh).

[220] The history of COVID–19 variable is used as part of our risk adjustment model which accounts for risk factors such as beneficiary age and other clinical risk factors. This variable has been added as a clinical risk factor due to effects of patient history of COVID–19 on readmission risk.

(that is, patients with history of COVID–19 are more likely to be readmitted) for the performance period.

Response: We thank the commenter for this input. Analyses using data from July 1, 2020 through February 28, 2021 showed that for most of the readmissions measures, observed (unadjusted) 30-day readmission rates for patients without an index admission of COVID–19, but with a history of COVID–19 (defined as U07.1 or Z86.16 in the 12 months prior to the admission, or Z86.16 at the index admission), were higher than patients without a history of COVID–19. Based on the higher odds of readmission for these patients, we decided to add the covariate across all of the readmission measures in the Hospital Readmissions Reduction Program. We are now providing updated information.

Results using more recent data spanning the entire 3-year reporting period (July 1, 2018 through June 30, 2021) showed that for patients without an index admission of COVID–19, those with a history of COVID–19 (defined in the previous paragraph) in the pneumonia and heart failure cohorts have much higher frequencies of some model risk variables compared with patients without a history of COVID–19, suggesting they are sicker. At the same time, in a multivariable model, we found, as the commenter notes, that unlike the bivariate relationship, the adjusted odds ratios for 30-day readmission for the history of COVID–19 variable (the odds ratios in the context of all the variables in the model) were less than one (for all but the Hospital 30-day RSSR following COPD hospitalization measure—NQF #1891). Therefore, in these patients without COVID–19 at the time of admission, but with a history of COVID–19, the non-COVID–19 clinical comorbidities in the risk model are lessening or reversing the effect size of the history of COVID–19 variable. We have decided, however, to keep the history of COVID covariate in the model for reasons of face validity and to account for any future risk adjustment for long COVID that may not be accounted for in the measures' baseline risk models. However, we will consider this recommendation as we continue to evaluate and update our measure specifications

Comment: A commenter opposed updates to measure specifications (that is, inclusion of a covariate adjustment to account for patient history of COVID–19 in the 12 months prior to the index admission and excluding patients with a diagnosis of COVID–19 present on admission from the pneumonia readmission measure) because these patients are vulnerable. This commenter stated that hospitals should be incentivized to care for this patient population.

Response: We agree with the commenter that it is important that these patients receive high quality care when hospitalized. However, we note that the measures in the Hospital Readmissions Reduction Program were developed and adopted to identify excess readmissions for patients hospitalized for specific conditions or procedures. Because COVID–19 did not exist when these measures were developed, the measures are neither intended nor specified to address the clinical needs of patients with a history of COVID–19. We will continue to assess specifications of the measures in the Hospital Readmissions Reduction Program to identify whether further updates to account for care provided to COVID–19 patients are appropriate.

Comment: A commenter requested clarification regarding whether the updates to the measure specifications, specifically inclusion of a covariate adjustment for patients who have had COVID–19 in the 12 months prior to the index admission for each of the six condition/procedure specific readmissions measures in the Hospital Readmissions Reduction Program and updating the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) to exclude patients with a diagnosis of COVID–19 present on admission from the measure denominator (cohort) and numerator (outcome), will be in effect after the end of the PHE or if this is a form of data suppression associated with the PHE.

Response: We have adopted this update as an update to the measure specifications, not as suppression of data related to the COVID–19 PHE. Therefore, the updated measure specifications will not necessarily change with the end of the PHE. However, we will continue to monitor the effects of COVID–19 on each of our measures and on the overall program to ensure that the measure specifications remain appropriate for evolving clinical practices.

Comment: A commenter expressed concern that the measure specifications are not publicly available and therefore commenters were unable to assess the impact of measure updates.

Response: We regret that the commenter was unable to find the measure specification information to assess the impact of measure updates. As described in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28421), the measure specifications, which were posted in May 2022, are available at *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*.

Because of the CMS 30 Day Pneumonia Readmission Measure (NQF #0506) being paused from program calculations for FY 2023, the methodology report for FY 2023 is not yet available. However, we believe that past methodology reports provide sufficient information on the measure's specifications that commenters were able to assess the impact of updates on this measure.

Comment: A commenter recommended risk adjusting for COVID–19 during an encounter instead of suppressing data for reporting periods or populations.

Response: We believe this commenter is recommending developing a risk adjustment methodology for patients admitted with a primary or secondary diagnosis of COVID–19 present at admission instead of excluding these patients from the numerator (outcome) and denominator (cohort). We thank the commenter for this suggestion. We will consider this option in the future as we continue to evaluate the effectiveness of our COVID–19 updates for the measures in the Hospital Readmissions Reduction Program.

Comment: Several commenters recommended that CMS publicly report the results of analyses that show that the data being used to capture patients with a history of COVID–19 in the 12 months prior to the index admission are sufficiently reliable. A commenter recommended that CMS publicly report analyses of the impact of COVID–19 patients on measure results to support public understanding of the results of measure updates.

Response: We agree with the commenters that publicly reporting analyses that support our updates to measure specifications advances our objective of transparency in program operations. We note that we have published our analyses to date in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28419 through 28421) and in response to public comments in this final rule.

6. Definition of ''Applicable Period''

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53375) for discussion of our previously finalized policy for defining ''applicable period.'' The definition of ''applicable period'' is also specified at 42 CFR 412.152. The ''applicable period'' is the 3-year period from which data are being collected in order to calculate excess readmission ratios (ERRs) and payment adjustment factors

for the fiscal year; this includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment. The ''applicable period'' for dually eligible beneficiaries is the same as the ''applicable period'' that we otherwise adopt for purposes of the Hospital Readmissions Reduction Program.

In order to provide greater certainty around future ''applicable periods'' for the Hospital Readmissions Reduction Program, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58845 through 58846), we finalized the automatic adoption of ''applicable periods'' for FY 2023 and all subsequent program years for the Hospital Readmissions Reduction Program.

Beginning in FY 2023, the ''applicable period'' for the Hospital Readmissions Reduction Program will be the 3-year period beginning 1 year advanced from the previous program fiscal year's start of the ''applicable period.'' [221] Under this policy, for all subsequent years, we will advance this 3-year period by 1 year unless otherwise specified by the Secretary, which we would convey through notice and comment rulemaking. Similarly, the ''applicable period'' for dual eligibility will continue to correspond to the ''applicable period'' for the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58845 through 58846) for a more detailed discussion of this topic.

In the FY 2023 IPPS/LTCH PPS proposed rule, we did not propose any updates to this policy.

7. Identification of Aggregate Payments for Each Condition/Procedure and All Discharges

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payment amount for an individual hospital for the applicable period for each condition/procedure using Medicare inpatient claims from the MedPAR file with discharge dates that are within the applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source.

In identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. For the FY 2023 applicable period, this includes the discharge diagnoses for each applicable condition/procedure based on a list of specific ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure.

We identify Medicare fee-for-service (FFS) claims that meet the criteria as previously described for each applicable condition/procedure to calculate the aggregate payments for excess readmissions. This means that services covered by Medicare Advantage are not included in this calculation. This policy is consistent with the methodology to calculate ERRs based solely on admissions and readmissions for Medicare FFS patients.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38232), we stated that we would determine the neutrality modifier using the most recently available full year of MedPAR data. For the purpose of modeling the estimated FY 2023 readmissions payment adjustment factors for this final rule, we would use the proportion of dually eligible beneficiaries, excess readmission ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2023 Hospital Readmissions Reduction Program applicable period (July 1, 2018 through June 30, 2021).[222]

For the FY 2023 program year, applicable hospitals will have the opportunity to review and correct calculations based on the FY 2023 applicable period of July 1, 2018 to June 30, 2021, before they are made public under our policy regarding reporting of hospital-specific information. Again, we reiterate that this period is intended to review the program calculations, and not the underlying data. For more information on the review and corrections process, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53401).

We did not propose any changes to our policies for the identification of aggregate payments for each condition/procedure in the FY 2023 IPPS/LTCH PPS proposed rule.

8. Use of MedPAR Data Corresponding to the Applicable Period

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387 through 53390) for discussion of our previously finalized policy for the use of MedPAR claims data as our data source for determining aggregate payments for each condition/procedure and aggregate payments for all discharges during applicable periods. Most recently, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45258), we finalized our policy on the continued use of the MedPAR data corresponding to the applicable period for the Hospital Readmissions Reduction Program calculations for the FY 2022 applicable period.

In addition, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45259), we expressed our continued belief that the use of MedPAR claims data is the appropriate source for identifying aggregate payments for each condition/procedure and all discharges during the corresponding applicable period for the Hospital Readmissions Reduction Program. Therefore, we finalized our proposal to automatically adopt the use of MedPAR data corresponding to the applicable period (the 3-year period beginning 1 year advanced from the previous program fiscal year's MedPAR data) [223] for Hospital Readmissions Reduction Program calculations for FY 2023 and all subsequent program years.

In the FY 2023 IPPS/LTCH PPS proposed rule, we did not propose any changes to this policy.

9. Calculation and Application of Payment Adjustment Factors

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within peer groups, based on the proportion of dually eligible beneficiaries served by each hospital, in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019. Section 1886(q)(3)(D) of the Act also states that this methodology could be

[221] Although the FY 2023 applicable period would be July 1, 2018 through June 30, 2021, we note that the first and second quarter data from CY 2020 is excluded from consideration for program calculation purposes due to nationwide ECE that was granted in response to the COVID–19 PHE.

[222] Although the FY 2023 applicable period is July 1, 2018, through June 30, 2021, we note that first and second quarter data from CY 2020 is excluded from consideration for program calculation purposes due to the nationwide ECE that was granted in response to the COVID–19 PHE.

[223] Although the FY 2023 applicable period is July 1, 2018, through June 30, 2021, we note that first and second quarter data from CY 2020 is excluded from consideration for program calculation purposes due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for calculating DRG payments would be adjusted to July 1, 2018 through December 1, 2019 and July 1, 2020 through June 30, 2021. Further information will be found in the FY 2023 Hospital Specific Report (HSR) User Guide located on QualityNet website at *https://qualitynet.cms.gov/inpatient/hrrp/reports.*

replaced through the application of subclause (E)(i), which states that the Secretary may take into account the studies conducted and the recommendations made by the reports required by section 2(d)(1) of the IMPACT Act of 2014 (Pub. L. 113–185; 42 U.S.C. 1395 note) with respect to risk adjustment methodologies.

Additionally, section 1886(q)(3)(A) of the Act defines the payment adjustment factor for an applicable hospital for a fiscal year as ''equal to the greater of: (i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).'' Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of aggregate payments for excess readmissions to aggregate payments for all discharges, scaled by the neutrality modifier. The calculation of this ratio is codified at 42 CFR 412.154(c)(l) and the floor adjustment factor is codified at 42 CFR 412.154(c)(2). Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, and codified in our regulations at 42 CFR 412.154(c)(2), for FY 2023, the payment adjustment factor will be either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2023, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) for a detailed discussion of the payment adjustment methodology. For additional information on Hospital Readmissions Reduction Program payment calculations, we refer readers to the Hospital Readmissions Reduction Program information and resources available on our QualityNet website.

We did not propose any changes to our calculation of payment methodology in the FY 2023 IPPS/LTCH PPS proposed rule.

10. Extraordinary Circumstance Exception (ECE) Policy for the Hospital Readmissions Reduction Program

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543), we adopted an ECE policy for the Hospital Readmissions Reduction Program, which recognized that there may be periods of time during which a hospital is not able to submit data (from which readmission measures data are derived) in an accurate or timely fashion due to an extraordinary circumstance beyond its control. When adopting this policy, we noted that we considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's excess readmission ratios for the applicable performance period. By minimizing the data excluded from the program, the policy enabled affected hospitals to continue to participate in the Hospital Readmissions Reduction Program for a given fiscal year if they otherwise continued to meet applicable measure minimum threshold requirements. We expressed the belief that this approach would help alleviate the burden for a hospital that might be adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the Hospital Readmissions Reduction Program. We further observed that section 1886(q)(5)(D) of the Act permits the Secretary to determine the applicable period for readmissions data collection, and we interpreted the statute to allow us to determine that the period not include times when hospitals may encounter extraordinary circumstances. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38239 through 38240), we modified the requirements for the Hospital Readmissions Reduction Program ECE policy to further align with the processes used by other quality reporting and VBP programs for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control.

In response to COVID–19, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based purchasing programs. On September 2, 2020, we published the interim final rule with comment period (IFC), ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820). The IFC updated the ECE we granted in response to the COVID–19 PHE, for the Hospital Readmissions Reduction Program and several other quality reporting programs (85 FR 54827 through 54837). In the IFC, we updated the previously announced application of our ECE policy for the Hospital Readmissions Reduction Program (85 FR 54832 through 54833) to the COVID–19 PHE to exclude any data submitted regarding care provided during the first and second quarters of CY 2020 from our calculation of performance for FY 2022, FY 2023, and FY 2024.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45260 through 45262), we clarified our ECE policy to highlight that an ECE granted under the Hospital Readmissions Reduction Program would exclude claims data during the corresponding ECE period. We stated that although we had considered the feasibility and implications of excluding data under the ECE policy for the Hospital Readmissions Reduction Program, we had never specified the types of data that would be excluded under an ECE granted to an individual hospital. Considering that the Hospital Readmissions Reduction Program only uses claims data, we clarified our ECE policy to specify that claims data will be excluded from calculations of measure performance under an approved ECE for the Hospital Readmissions Reduction Program. We further clarified that although an approved ECE for the Hospital Readmissions Reduction Program would exclude excepted data from Hospital Readmissions Reduction Program payment reduction calculations, we did not waive the data submission requirements of a hospital for claims data (86 FR 45261 through 45262). For example, for claims data, we require a hospital to submit claims to receive payments for the services they provided to patients. Although an individual ECE approval under the Hospital Readmissions Reduction Program would except data submitted by a hospital from Hospital Readmissions Reduction Program calculations, a hospital would still need to submit its claims in order to receive payment outside the scope of the Hospital Readmissions Reduction Program for services provided.

Finally, in the FY 2022 IPPS/LTCH PPS final rule, we clarified that, although an approved ECE for the Hospital Readmissions Reduction Program would exclude excepted data from Hospital Readmissions Reduction Program payment reduction calculations, such an ECE does not exempt hospitals from payment reductions under the Hospital Readmissions Reduction Program (86 FR 45262).

We did not propose any changes to our previously finalized ECE Policy in the FY 2023 IPPS/LTCH PPS proposed rule.

11. Request for Public Comment on Possible Future Inclusion of Health Equity Performance in the Hospital Readmissions Reduction Program

We are committed to achieving equity in healthcare outcomes for our beneficiaries by supporting providers' quality improvement activities to reduce health inequities, by enabling them to make more informed decisions, and by promoting provider accountability for healthcare disparities.[224] As described in section IX.B. of the preamble of this final rule, we discussed and sought comment on overarching principles for measuring health care quality disparities to provide more actionable and comprehensive information on health care disparities across multiple social risk factors and demographic variables. As part of this request for information, we also discussed different approaches for identifying meaningful performance differences and guiding principles for reporting disparity measures.

As previously discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals with differing proportions of dually eligible beneficiaries in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019. To implement this provision, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237), we finalized a number of changes to the payment reduction methodology, including our policy to stratify hospitals into quintiles, or peer groups, based on their proportion of dually eligible beneficiaries (82 FR 38229 through 38231) and our policy to use the median excess readmission ratio for the hospital's peer group in place of 1.0 in the payment reduction formula (82 FR 38231 through 38237). In this peer grouping methodology, dual eligibility status is used as it is an indicator of beneficiaries' social risk. The peer grouping methodology mitigates against disproportionate payment reductions for hospitals serving socially at-risk populations. However, this peer grouping methodology does not directly measure or account for disparities in health care quality between beneficiary groups with heightened social risk and groups with less social risk.

In the FY 2018 IPPS/LTCH PPS final rule, we introduced confidential reporting of hospital quality measure data stratified by social risk factors (82 FR 38403 through 38409). We have created two complementary methods to calculate disparities in condition/procedure-specific readmission measures (the CMS Disparity Methods). The first method (the Within-Hospital disparity method) promotes quality improvement by calculating differences in outcome rates across beneficiary groups within a hospital while accounting for their clinical risk factors. This method also allows for comparison of those differences, or disparities, across hospitals, so hospitals could assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital method) assesses hospitals' outcome rates for subgroups of beneficiaries across hospitals, allowing for a comparison across hospitals on their performance serving beneficiaries with social risk factors. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the Disparity Methods technical report and Updates and Specifications Report posted on the QualityNet website for additional details. The CMS Disparity Methods more directly measure disparities in health care quality between dually eligible and non-dually eligible beneficiary groups than the Hospital Readmissions Reduction Program's peer grouping methodology. For example, when considering the CMS Disparity Methods results calculated using data for the FY 2022 Hospital Readmissions Reduction Program performance period, measures showed not only a range between low and high disparity rates within hospitals, but also worse overall outcome rates for beneficiaries with social risk using beneficiary dual eligibility status as the stratification variable. Of these measures, the most actionable for hospitals were measures that showed overall high readmission rates for dually eligible beneficiaries across hospitals, or a large difference in readmission rates between dually eligible and non-dually eligible beneficiaries. These gaps in care indicated that there is potential for improvement, or a reduction in disparity at poorly performing hospitals if they were able to emulate the performance of strongly performing hospitals.

The Hospital Readmissions Reduction Program currently groups hospitals into one of five peer groups based on their proportion of beneficiaries who are dually eligible for Medicare and full Medicaid benefits. Beneficiaries' dual eligibility for Medicare and Medicaid is a widely used proxy for a beneficiary's financial risk. Medicaid enrollees have incomes and overall wealth below a certain threshold and thus, Medicaid eligibility may be used as a proxy for low socioeconomic status. The use of beneficiaries' dual eligibility in social risk factor analyses was supported by ASPE's First Report to Congress.[225] This report found that in the context of value-based purchasing programs such as the Hospital Readmissions Reduction Program, dual eligibility, as an indicator of social risk, was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested. In alignment with the current program, we are considering the use of the beneficiary's dual eligibility status as a measure of beneficiaries' social risk that could be used to incorporate hospitals' performance for socially at-risk populations in the Hospital Readmissions Reduction Program.

As part of our broader goal of achieving equity in healthcare outcomes for our beneficiaries, we are interested in encouraging providers to improve health equity and reduce health care disparities through the Hospital Readmissions Reduction Program. We sought comment on approaches to updating the Hospital Readmissions Reduction Program to incorporate performance for socially at-risk populations. For example, we are considering approaches that would account for a hospital's performance on readmissions for socially at-risk beneficiaries compared to all other hospitals, or its performance in treating socially at-risk beneficiaries compared to other beneficiaries within the hospital, or combinations of these approaches. We acknowledge that updating the Hospital Readmissions Reduction Program to encourage improved performance for socially at-risk populations can take many forms, and we sought to explore different approaches so we can find an approach that satisfies our goals without unintended consequences.

In exploring approaches to incorporate performance for socially at-risk populations in the Hospital Readmissions Reduction Program, our objective is to encourage providers to improve health equity and reduce health care disparities without

[224] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

[225] Office of the Assistant Secretary for Planning and Evaluation. (2016). Social risk factors and performance under Medicare's value-based purchasing programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

disincentivizing hospitals to treat socially at-risk beneficiaries or disproportionately penalizing hospitals that treat a large proportion of socially at-risk beneficiaries. We sought comment on approaches that would achieve this objective.

As also discussed in our request for information on overarching principles for measuring health care quality disparities, as described in section IX.C of the preamble of this final rule, many non-clinical drivers of health are known to impact beneficiary outcomes, including social risk factors such as socioeconomic status, housing security and adequacy, and food security. The Hospital Readmissions Reduction Program currently uses beneficiaries' dual eligibility for Medicare and Medicaid as a proxy for a beneficiary's social risk and uses dual eligibility, as required by the statute, to divide hospitals into peer groups for comparison under the program. We sought comment on variables associated with or measures of social risk and beneficiary demographics that are already collected, as well as broader definitions of dual eligibility, such as those who are enrolled in a Medicare Savings Program or the Medicare Part D Low Income Subsidy, that could be included in the Hospital Readmissions Reduction Program in addition to dual eligibility. We note initially we would use such variables to stratify results within Hospital Specific Reports (HSRs) as confidential feedback to hospitals.

Measures of social risk could also include indices developed for the purpose of identifying socially at-risk populations and measuring the degree of risk. For example, as described in section IX.B, we are considering the University of Wisconsin School of Medicine and Public Health and Health Resources and Services Administration's Area Deprivation Index (ADI),[226] Agency for Healthcare Research and Quality Socioeconomic Status Index,[227] and the Centers for Disease Control and Prevention's Social Vulnerability Index.[228] For example, the ADI allows for rankings of neighborhoods by socioeconomic disadvantage in a region of interest (such as at the state or national level), and includes factors for income, education, employment, and housing quality and is used in our Everyone with Diabetes Counts program in order to target seniors in the most disadvantaged neighborhoods for diabetes education.[229] In addition to individual variables or sets of variables we sought comment on the addition of one or more of these indices or proposals for other indices or modified indices that capture multiple dimensions of social risk and that have demonstrated relations to health outcomes or access to health care resources, that can be added to the Program along with dual eligibility as factors for stratifying data. We requested commenters to include information on the availability of public data sources and documentation of the methods and testing that establish their applicability and provide supporting information about availability and methods when suggesting variables or indices to measure social risk. Support from a national-level assessment of the impact of social risk can be particularly useful to demonstrate the relevance of a proposed indicator.

Before any changes to the Hospital Readmissions Reduction Program are implemented, we plan to assess the extent to which they address our objective as well as their financial impact on the Hospital Readmissions Reduction Program. Any proposals to update the Hospital Readmissions Reduction Program to account for the extent to which a hospital is able to provide high quality and equitable care for beneficiaries with social risk factors, as previously described, would be made through future rulemaking.

We invited public comment on the following: (1) the benefit and potential risks, unintended consequences, and costs of incorporating hospital performance for beneficiaries with social risk factors in the Hospital Readmissions Reduction Program; (2) the approach of linking performance in caring for socially at-risk populations and payment reductions by calculating the reductions based on readmission outcomes for socially at-risk beneficiaries compared to other hospitals or compared to performance for other beneficiaries within the hospital; and (3) measures or indices of social risk, in addition to dual eligibility, that should be used to measure hospitals' performance in achieving equity in the Hospital Readmissions Reduction Program.

We received comments in response to this request for information and have summarized them here.

Comment: Several commenters provided general comments regarding equity in the Hospital Readmissions Reduction Program. Some of these commenters expressed concern that current disparity methods lack actionable information. A commenter recommended providing financial support to prevent readmissions related to social needs, for example, by supporting hospitals' efforts to monitor post discharge outcomes and connect patients with necessary services. A commenter observed that hospitals are still experiencing the effects of the COVID–19 PHE and recommended that CMS wait until these effects have subsided to introduce new payment calculations both to ensure that any calculations are based on reliable data and to prevent further overwhelming hospitals.

Many commenters responded to our request for input on the benefit and potential risks, unintended consequences, and costs of incorporating hospital performance for beneficiaries with social risk factors in the Hospital Readmissions Reduction Program. Several commenters expressed that the potential benefits of incorporating equity in the Hospital Readmissions Reduction Program are improved care for at-risk patients, improved understanding of the effects of the social risk factors, and improved care for all patients. A commenter stated that readmissions are a metric for healthcare equity because patients who receive high quality care are generally not readmitted. This commenter expressed that improving healthcare equity could reduce readmissions.

Many commenters expressed the concern that linking payment to performance on equity measures may disproportionately penalize safety net hospitals or other providers that treat high complexity patients which could impact access and quality for these patients. Some of these commenters recommended using bonus points or incentives to avoid penalizing hospitals that treat at-risk patients. A commenter observed that addressing disparities will require a long-term systemic approach.

Many commenters expressed concern that incorporating performance for beneficiaries with social risk factors in

[226] Center for Health Disparities Research. About the Neighborhood Atlas. Available at: *https://www.neighborhoodatlas.medicine.wisc.edu/*.

[227] Bonito A., Bann C., Eicheldinger C., Carpenter L. (2008). Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare & Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality.

[228] Flanagan, B.E., Gregory, E.W., Hallisey, E.J., Heitgerd, J.L., Lewis, B. (2011). A social vulnerability index for disaster management. Journal of Homeland Security and Emergency Management, 8(1). Available at: *https://www.atsdr.cdc.gov/placeandhealth/svi/img/pdf/Flanagan_2011_SVIforDisasterManagement-508.pdf*.

[229] *https://www.neighborhoodatlas.medicine.wisc.edu/*.

the Hospital Readmissions Reduction Program could lead hospitals to be held accountable for factors outside of their control. These commenters specifically noted that there are numerous factors outside of a hospitals' control that affect readmission rates, including community and patient level factors. Some of these commenters recommended developing a mechanism for adjusting for confounding influences to ensure public reporting and payment are based exclusively on the quality of care provided; one of these commenters specifically recommended adopting a risk adjustment for patients who do not take responsibility for their post discharge care. Other commenters recommended against public reporting on stratified or other equity data because this publication could imply that hospitals are solely responsible for 30-day readmissions.

Several commenters observed that analyzing data does not address the underlying disparities, it only allows the extent of the issue to be understood. A commenter stated that publicly reporting all data, both as trend reports and as raw data, allows advocates and other interested parties to perform analyses and evaluate equity.

Several commenters observed that the current peer grouping and stratified reporting are recent changes to the Hospital Readmissions Reduction Program, and that much of the recent data for the Program has been affected by the COVID–19 PHE. These commenters recommended leaving the payment structure unchanged for at least three more years to analyze the effects of the current program prior to modifying the payment structure. A commenter stated the belief that the Hospital Readmissions Reduction Program methodology is flawed because it uses point estimates of risk-standardized readmission rates without respect to the margin of error for each estimate. This commenter requested clarification regarding the expectations for hospitals prior to including care for at-risk patients into the Hospital Readmission Reduction Program methodology. Another commenter observed that the current payment calculations are already complex and expressed concern that further modification to a complex system could lead to unintended consequences.

Several commenters stated that linking payment to equity is inconsistent with the statutory requirements for calculating payment reductions. Some of these commenters observed that the payment system was designed to ensure equitable payments for hospitals that treat high risk patients, not to advance patient level equity in outcomes. Several commenters observed that tracking drivers of health data may increase the burden for providers. A commenter expressed concern that linking payment to performance on equity measures would change hospitals' focus to factors outside of each patient's medical diagnosis, thereby decreasing the quality of care. A commenter expressed concern that the measures in the Hospital Readmissions Reduction Program already require three years of data to ensure sufficient sample sizes, therefore this commenter is concerned that stratification of these measures could lead to samples too small to be reliable.

A commenter stated that without uniformly collected patient-reported sociodemographic data there is not a data source sufficiently reliable for inclusion in payment adjustments. This commenter observed that the NQF is preparing to release guidance on using ADI and other social risk factor data for quality measurement which may provide useful information for the Hospital Readmissions Reduction Program to consider. Another commenter recommended rigorous statistical testing prior to adopting any health equity methodologies.

Several commenters responded to our request for input on the approach of linking performance in caring for socially at-risk populations and payment reductions by calculating the reductions based on readmission outcomes for socially at-risk beneficiaries compared to other hospitals or compared to performance for other beneficiaries within the hospital. Several of these commenters recommended that any use of the Across-Hospital Disparity method comparison should only compare hospitals within similar communities because community resources are an important factor in readmission risk. A commenter recommended starting with the Across-Hospital Disparity method because this is more likely to account for factors outside of a hospital's control that affect readmission rates. Another commenter recommended starting with Within-Hospital Disparity method because these data will be easier for CMS to calculate and easier for hospitals to understand.

Several commenters supported providing both Within- and Across-Hospital Disparity methods, but only in confidential reports for hospitals. One of these commenters stated that CMS does not have the statutory authority to include these data in Hospital Readmissions Reduction Program payment calculations. Other commenters observed that including Within- and Across-Hospital Disparity method performance in a hospital's readmission score (as opposed to in the measures' risk adjustment methodologies) is inconsistent with CMS's approach to clinical risk factors, specifically noting that for clinical risk factors CMS recognizes that these factors are largely beyond a hospital's control and therefore includes them in the risk adjustment methodology.

Many commenters provided input to our request for potential measures or indices of social risk, in addition to dual eligibility, that should be used to measure hospitals' performance in achieving equity in the Hospital Readmissions Reduction Program. Many commenters observed that the Hospital IQR Program has proposed a Screen Positive Rate for Social Drivers of Health (SDOH) measure in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28503 through 87 28506). These commenters observed that the patient-level data collected by hospitals for these measures may be appropriate for stratification or other analysis in the Hospital Readmissions Reduction Program.

Several commenters expressed concern regarding the use of dual eligibility for Medicare and Medicaid coverage as a proxy variable. These commenters observed that Medicaid eligibility requirements vary from state to state and therefore is not a nationally comparable metric. One of these commenters supported including eligibility for the Medicare Savings Program or the Medicare Part D Low Income Subsidy in analyses. Another commenter expressed concern that disability may be another aspect of dual eligibility that influences readmissions, and that using dual eligibility as a proxy for income may hinder analysis of the effects of disability.

Many commenters supported the use of proxy measures (including dual eligible status, the ADI, the Social Vulnerability Index, the Neighborhood Deprivation Index, the Multidimensional Deprivation Index, or a custom developed index specifically related to health equity) as a short term solution until CMS can report data based on clearly and consistently defined patient-level, patient-collected data (including race, age, disability, sex, sexual orientation, and gender identity, limited English proficiency, primary language, housing instability, and marital status). Several commenters observed that there may be challenges to patient-level data collection, including technological challenges and patient discomfort with sharing sensitive

information. A few commenters recommended including the ADI with other, patient-level data in analyses to ensure that use of the ADI does not further disparities such as by providing data indicating specific communities need greater support, but not providing data regarding the subpopulations within those communities that require the most support. A commenter observed that available indices do not account for the role of segregation, gentrification, and hypersegregation in health outcomes. A commenter expressed concern that use of multiple factors or indices could create contradictory analytical findings. Without detailed explanation for these contradictory results, there could be stakeholder confusion. A commenter recommended considering how to incorporate data collected on claims using z-codes to analyze readmissions in the Hospital Readmissions Reduction Program. Another commenter recommended combining the analysis of social and clinical data to identify gaps in care. A commenter observed that the factors that affect disparities are systemic, community, institutional, interpersonal, and intrapersonal and recommended that CMS consider all factors.

Several commenters agreed that non-clinical factors may affect readmissions and recommended conducting analyses to determine which factors and to what degree prior to incorporating these factors into the Hospital Readmissions Reduction Program. Several commenters recommended using patient-level social risk variables (such as race, age, disability, sex, sexual orientation, and gender identity, limited English proficiency, primary language, housing instability, and marital status) for peer grouping. A commenter recommended using stratification for analysis. A commenter recommended that CMS evaluate hospitals' community investments.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity efforts. For more information on our ongoing effort we refer readers to our recently released CMS National Quality Strategy (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*) and the CMS Framework for Health Equity (*https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity*) in which we describe our five priorities for advancing health equity.

I. Hospital Value-Based Purchasing (VBP) Program: Policy Changes

Section 1886(o) of the Act requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to our codified requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.168.

1. Flexibilities for the Hospital VBP Program in Response to the Public Health Emergency (PHE) Due to COVID–19

a. Measure Suppression Policy for the Duration of the COVID–19 PHE

In the FY 2022 IPPS/LTCH PPS final rule, we finalized a measure suppression policy and several Measure Suppression Factors for the duration of the COVID–19 PHE (86 FR 45266 through 45269). We stated that we had previously identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating hospitals' control. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors, such as the COVID–19 PHE.

Specifically, we finalized a policy for the duration of the COVID–19 PHE that enables us to suppress the use of data for a number of measures if we determine that circumstances caused by the COVID–19 PHE have affected those measures and the resulting Total Performance Scores (TPSs) significantly. We also finalized the adoption of Measure Suppression Factors which will guide our determination of whether to suppress a Hospital VBP Program measure for one or more program years where the baseline or performance period of the measure overlaps with the COVID–19 PHE. The finalized Measure Suppression Factors are as follows:

- Measure Suppression Factor 1: Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Measure Suppression Factor 2: Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.
- Measure Suppression Factor 3: Rapid or unprecedented changes in—
  - ++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
  - ++ The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.
- Measure Suppression Factor 4: Significant national shortages or rapid or unprecedented changes in—
  - ++ Healthcare personnel;
  - ++ Medical supplies, equipment, or diagnostic tools or materials; or
  - ++ Patient case volumes or facility-level case mix.

We also note that, as part of this measure suppression policy, we stated that we would still provide confidential feedback reports to hospitals on their measure rates on all measures to ensure that they are made aware of the changes in performance rates that we have observed. We also stated that we would publicly report suppressed data with appropriate caveats noting the limitations of the data due to the COVID–19 PHE. We continue to strongly believe that publicly reporting these data will balance our responsibility to provide transparency to consumers and uphold safety while ensuring that hospitals are not unfairly scored or penalized through payment under the Hospital VBP Program. We also note that, due to operational complications associated with the proposed changes to the scoring methodology, and in order to allow enough time for the appropriate notice and comment period process, we may not be able to provide hospitals with the feedback reports for FY 2023 until after August 1, 2022. We intend to provide hospitals with these feedback reports for FY 2023 as soon as possible and estimate that we will be able to provide reports before the end of 2022.

We did not propose any changes to the measure suppression policy.

b. Suppression of Specific Measures for the FY 2023 Program Year

(1) Background and Overview

COVID–19 has had significant negative health effects—on individuals,

communities, nations, and globally. Consequences for individuals who have COVID–19 include morbidity, hospitalization, mortality, and post-COVID–19 related conditions (also known as long COVID). As of June 2022, over 86 million COVID–19 cases, 4.8 million new COVID–19 related hospitalizations, and 1 million COVID–19 deaths have been reported in the U.S.[230] One analysis projected that COVID–19 would reduce life expectancy in 2020 by 1.13 years overall, with the estimated impact disproportionately affecting minority communities. According to this analysis, the estimated life expectancy reduction for Black and Latino populations is 3 to 4 times the estimate when comparing to the white population.[231] With a death toll surpassing that of the 1918 influenza pandemic, COVID–19 is the deadliest disease in American history.[232]

Additionally, impacts of the COVID–19 pandemic have continued to accelerate in 2021 as compared with 2020. The Delta variant of COVID–19 (B.1.617.2) surfaced in the United States in early-to-mid 2021. Studies have shown that the Delta variant is up to 60 percent more transmissible than the previously dominant Alpha variant in 2020.[233] Further, in November 2021, the number of COVID–19 deaths for 2021 surpassed the total deaths for 2020. According to CDC data, the total number of deaths involving COVID–19 reached 385,453 in 2020 and 451,475 in 2021.[234] With this increased transmissibility and morbidity associated with the Delta variant as well as new variants like Omicron which have impacted 2021 [235] [236] and worsening staffing shortages in Q3 and Q4 2021 associated with the ongoing PHE,[237] we remain concerned about using measure data that is significantly impacted by COVID–19 for scoring and payment purposes for the FY 2023 program year.

As noted in section V.H.1.a., in the FY 2022 IPPS/LTCH PPS final rule, we finalized a measure suppression policy and several Measure Suppression Factors for the duration of the COVID–19 PHE (86 FR 45266 through 45269). In addition, under that policy, we suppressed the following measures for the FY 2022 program year:

- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (NQF #0166)
- Medicare Spending per Beneficiary—Hospital (MSPB) (NQF #2158)
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
- American College of Surgeons-Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcomes Measure (NQF #1716)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

Since the publication of the FY 2022 IPPS/LTCH PPS final rule, we have conducted analyses on all Hospital VBP Program measures to determine whether and how COVID–19 has impacted the validity of the data used to calculate these measures for the FY 2023 program year. Our discussion of the findings from these analyses follows. Based on those analyses, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28426 through 28445), we proposed to suppress the following measures for the FY 2023 program year:

- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (NQF #0166)
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
- American College of Surgeons-Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

We also note that in the FY 2022 IPPS/LTCH PPS final rule, we finalized our proposal to suppress the Hospital 30-Day, All Cause, Risk Standardized Mortality Rate Following Pneumonia (PN) Hospitalization measure (NQF #0468) (MORT–30–PN) for the FY 2023 program year (86 FR 45274 through 45276).

(2) Suppression of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure (NQF #0166) for the FY 2023 Hospital VBP Program Year

As noted in section V.H.1.b. of the preamble of this final rule, in the FY 2022 IPPS/LTCH PPS final rule, we finalized the suppression of the HCAHPS measure for the FY 2022 program year under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. We refer readers to the FY 2022 IPPS/LTCH PPS final rule for additional details and a summary of public comments we received related to that finalized policy (86 FR 45270 through 45271).

In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to suppress the HCAHPS measure for the FY 2023 program year under Measure Suppression Factor 1, significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years, and Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in healthcare

[230] *https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/index.html.*

[231] Andrasfay, T., & Goldman, N. (2021). Reductions in 2020 US life expectancy due to COVID–19 and the disproportionate impact on the Black and Latino populations. Proceedings of the National Academy of Sciences of the United States of America, 118(5), e2014746118. *https://www.pnas.org/content/118/5/e2014746118.*

[232] Covid overtakes 1918 Spanish flu as deadliest disease in U.S. history (*statnews.com*).

[233] Allen H., Vusirikala A., Flannagan J., et al. Increased Household Transmission of COVID–19 cases associated with SARS–CoV–2 Variant of Concern B.1.617.2: a national case-control study. Public Health England. 2021.

[234] *https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm.*

[235] *https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/mathematical-modeling-outbreak.html.*

[236] *https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html?s_cid=11734:omicron%20variant:sem.ga:p:RG:GM:gen:PTN:FY22.*

[237] Bloomberg, U.S. Hospital Staff Shortages Hit Most in a Year on Covid Surge, *https://www.bloomberg.com/news/articles/2022-01-05/one-in-five-u-s-hospitals-face-staffing-shortages-most-in-year* (citing HHS data).

personnel (87 FR 28427 through 28429). We would calculate hospitals' HCAHPS measure rates, but we would not use these measure rates to generate achievement, improvement, or consistency points for this measure.

Additionally, because the HCAHPS measure is the only measure included in the Person and Family Engagement domain, we would not calculate hospitals' FY 2023 domain scores for the Person and Family Engagement domain. Participating hospitals would continue to report the measure data to CMS so that we can monitor the effect of the circumstances on quality measurement and consider appropriate policies in the future. We would continue to provide confidential feedback reports to hospitals as part of program activities to allow hospitals to track the changes in performance rates that we observe. We also intend to publicly report CY 2021 measure rate data where feasible and appropriately caveated. As noted in section V.I.1.a. of the preamble of this final rule, we believe that publicly reporting suppressed measure data is an important step in providing transparency and upholding the quality of care and safety for consumers.

Based on our analysis of HCAHPS data from Q1 2019 to Q3 2021, we continue to observe a sustained decline in hospital-level HCAHPS scores beginning in Q2 2020. This decline is associated with the COVID–19 PHE in 2020 and 2021. HCAHPS measure results are publicly reported as ''top-box'', ''bottom-box'', and ''middle-box'' scores, with ''top-box'' being the most positive response to HCAHPS Survey items.[238]

In order to determine whether the COVID–19 PHE impacted the HCAHPS measure for the FY 2023 program year and to what extent, we conducted an analysis that compared the Q1 2021, Q2 2021, and Q3 2021 HCAHPS data to the Q1 2019, Q2 2019, and Q3 2019 HCAHPS data.[239] This analysis was similar to the analysis we conducted last year when we compared Q1 2020 and Q2 2020 HCAHPS data to Q1 2019 and Q2 2019 HCAHPS data.[240] As reflected in Table V.I.–01, this analysis showed that HCAHPS measure top-box scores in Q1, Q2, and Q3 2021 compared to the same quarter in pre-COVID–19 2019 were almost always lower. The relatively steady decline in HCAHPS top-box scores that began in Q2 2020 became sharper in Q3 2021. Compared to Q3 2019, HCAHPS scores in Q3 2021 were lower by 1 to 4 top-box points. These changes were statistically significant for all HCAHPS measures in Q2 2021 and Q3 2021 at the $p<0.0001$ level, meaning that changes were too large to occur by chance more than one time in 10,000.[241] These changes stand in sharp contrast to the pattern of generally small improvements prior to Q2 2020.

We believe that the analysis of Q1, Q2, and Q3 2021 HCAHPS scores indicates a pattern of significant negative changes in hospital performance from the immediately preceding pre-COVID–19 quarters where HCAHPS scores generally changed by less than 1 top-box point, sometimes increasing and sometimes decreasing, compared to the same quarter one year earlier.

TABLE V.I.-01: CHANGE IN HCAHPS TOP-BOX SCORES IN MATCHED QUARTERS FROM Q1 2020 VS. Q1 2019, TO Q3 2021 VS. Q3 2019

HCAHPS Measure used in the Hospital VBP Program	COVID-19 QUARTERS Change in HCAHPS Top-Box Points						
	Q1 2020 vs. Q1 2019	Q2 2020 vs. Q2 2019	Q3 2020 vs. Q3 2019	Q4 2020 vs. Q4 2019	Q1 2021 vs. Q1 2019	Q2 2021 vs. Q2 2019	Q3 2021 vs. Q3 2019
Communication with Nurses	-0.04	**-1.15*****	**-1.40*****	**-1.09*****	**-1.41*****	**-1.30*****	**-2.04*****
Communication with Doctors	0.00	**-0.91*****	**-1.06*****	**-0.78*****	**-0.90*****	**-1.02*****	**-1.67*****
Staff Responsiveness	**-0.82***	**-2.06*****	**-2.54*****	**-2.99*****	**-2.79*****	**-2.61*****	**-4.39*****
Communication About Medicine	**-1.23*****	**-3.27*****	**-3.05*****	**-2.12*****	**-2.68*****	**-2.67*****	**-3.84*****
Cleanliness	**-0.63*****	**-0.92*****	**-2.44*****	**-2.70*****	**-2.02*****	**-2.21*****	**-3.70*****
Quietness	**0.41****	**0.54*****	**-0.20***	**0.46*****	0.17	**-0.87*****	**-1.34*****
Discharge Information	**0.20****	**-0.79*****	**-0.69*****	**-0.76*****	**-0.52*****	**-0.59*****	**-1.02*****
Care Transition	**0.25****	**-2.00*****	**-1.96*****	**-1.63*****	**-1.42*****	**-1.26*****	**-2.06*****
Overall Rating	**0.77*****	-0.19	**-1.41*****	**-0.70*****	**-0.80*****	**-1.56*****	**-2.64*****
Number of hospitals in each pair of matched quarters	1606	1701	3074	3117	3129	3084	3084

*Significant at $p<0.05$; **Significant at $p<0.005$; ***Significant at $p<0.0001$. All bolded values are statistically significant.

Notes: Approximately 90% of hospitals in the Q3 2021 vs. Q3 2019 comparison are IPPS hospitals. Standard HCAHPS scoring, including survey mode and patient-mix adjustment, has been applied. Each column compares data from the named quarter (Q1 2020 to Q3 2021) to data from the same hospitals in the same quarter of 2019, thus accounting for seasonal effects and patient-mix adjustment.

We also proposed to suppress the HCAHPS measure for the FY 2023 program year under Measure Suppression Factor 4, significant national shortage or rapid or unprecedented changes in healthcare personnel. During the course of the PHE, an unprecedented number of healthcare personnel have left the workforce or ended their employment in hospitals.[242] This healthcare personnel shortage worsened in 2021, with hospitals across the United States reporting 296,466 days of critical staffing shortages, an increase of 86 percent from the 159,320 days of critical staffing shortage hospitals reported in

[238] Summary Analyses (*hcahpsonline.org*): *https://www.hcahpsonline.org/en/summary-analyses/*.

[239] We note that the COVID–19 PHE was declared on January 31, 2020: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[240] As described further in the FY 2022 IPPS/LTCH PPS final rule, in order to detect the possible impact of the COVID–19 PHE on patients' experience of hospital care, we previously conducted an ''apples-to-apples'' analysis in which we compared hospitals' HCAHPS measure top-box scores for each quarter between Q1 2019 and Q4 2020 to their top-box scores for each of the same quarters one year earlier (86 FR 45270 through 45271). We refer readers to the FY 2022 IPPS/LTCH PPS final rule for additional details on that analysis (86 FR 45270 through 45271).

[241] Comparisons for this analysis are based on hospitals with at least 25 completed surveys in each of the two matched quarters.

2020.[243] Healthcare workers, especially those in areas with higher infection rates, have reported serious psychological symptoms, including anxiety, depression, and burnout.[244] [245]

Shortages in hospital healthcare personnel have been shown to affect quality of care and patient satisfaction. Studies have shown that hospitals with greater numbers of hospitalists treating general-medicine patients and greater availability of nursing unit support services have been associated with higher levels of patient satisfaction.[246] [247] Conversely, nurse burnout has been linked to lower nurse-assessed quality of care [248] and lower patient satisfaction.[249] Nursing shortages have also been linked with negative patient perceptions of care.[250] Therefore, we believe this significant national change in healthcare personnel due to the COVID–19 PHE has significantly impacted hospitals' scores on the HCAHPS measure, which measures patient experience of hospital care, including staff responsiveness, communication with hospital staff, and cleanliness of the hospital environment.

Additionally, reports of hospital staff shortages have varied widely geographically. In January 2021, half of the hospitals in New Mexico and over 40 percent of the hospitals in Vermont, Rhode Island, West Virginia, and Arizona reported staffing shortages.[251] Conversely, in that same week, less than 10 percent of hospitals in Washington, DC, Connecticut, Alaska, Illinois, New York, Maine, Montana, Idaho, Texas, South Dakota and Utah reported staffing shortages. Given the wide variance in reported staffing shortages, and the impact staffing shortages has had on HCAHPS scores, we believe our proposal to suppress the HCAHPS measure fairly addresses the geographic disparity in the impact of the COVID–19 PHE on participating hospitals.

Due to the emergence of COVID–19 variants, such as the Delta variant, which worsened staffing shortages in Q3 and Q4 2021,[252] we anticipate that Q4 2021 data will continue to demonstrate a deviation in national performance such that scoring this measure would not be representative of national or individual hospital quality of care. Additionally, we believe that suppressing the HCAHPS measure is appropriate because the impact of COVID–19 on the measure cannot be addressed through risk adjustment for two reasons. First, we cannot risk adjust the measure to exclude patients whose admissions were related to COVID–19 because this measure does not capture patient-level diagnosis data. Second, even if we could exclude patients whose admissions were related to COVID–19 from the measure, we believe the HCAHPS calculations would still be impacted because hospital staffing and resource issues affect a hospital's entire patient population. Therefore, we believe that suppressing this measure for the FY 2023 program year will address concerns about the potential unintended consequences of penalizing hospitals that treated COVID–19 diagnosed patients.

For these reasons, we proposed to suppress the HCAHPS measure for the FY 2023 Hospital VBP Program year for purposes of scoring and payment under Measure Suppression Factors 1 and 4.

We welcomed public comment on this proposal.

Comment: Many commenters supported our proposal to suppress the HCAHPS measure, agreeing with our goal of ensuring that hospitals are not penalized or rewarded for quality measurement that was impacted by the COVID–19 PHE.

Response: We thank commenters for their support in suppressing the HCAHPS measure for scoring and payment purposes.

Comment: Several commenters did not support suppressing HCAHPS calculations because they believe that the need for transparency was more important. Commenters noted that patients should be aware of changes in the natural environment including due to the COVID–19 PHE.

Response: We appreciate and agree with commenters' concern about the need for transparency. As discussed in this final rule, although the HCAHPS measure is suppressed for the purposes of scoring and payment adjustments, we will make the data publicly available where feasible and appropriately caveated, recognizing the importance of transparency. We believe that publicly reporting these data will balance our responsibility to provide transparency to consumers, while ensuring hospitals are not unfairly scored or penalized.

Comment: A few commenters did not support our proposal to suppress the HCAHPS measure for the FY 2023 program year because they believe that suppressing measures does not incentivize resilience, noting that hospitals have had two years to adapt to the pandemic.

Response: Although we agree that building a more resilient health care system is necessary to avoid future threats to patient safety,[253] we believe that suppressing the HCAHPS measure for the FY 2023 program year offers hospitals the flexibility to focus on delivery of care while also accounting for the changing conditions during a PHE that are beyond hospitals' control. As we note previously, our goal is to resume the use of measure data for scoring and payment adjustment purposes beginning with the FY 2024 program year.

Comment: A commenter did not support suppressing entire data and reporting periods, noting widespread suppression, and instead recommended

[242] Health Affairs, *COVID–19's Impact on Nursing Shortages, The Rise of Travel Nurses, and Price Gouging* (Jan. 28, 2022), *https://www.healthaffairs.org/do/10.1377/forefront.20220125.695159/.*

[243] *https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/g62h-syeh.*

[244] Kriti Prasad, Colleen McLoughlin, Martin Stillman, Sara Poplau, Elizabeth Goelz, Sam Taylor, Nancy Nankivil, Roger Brown, Mark Linzer, Kyra Cappelucci, Michael Barbouche, Christine A. Sinsky. Prevalence and correlates of stress and burnout among U.S. healthcare workers during the COVID–19 pandemic: A national cross-sectional survey study. EClinicalMedicine, Volume 35. 2021. 100879. ISSN 2589–5370. *https://doi.org/10.1016/j.eclinm.2021.100879.*

[245] Vizheh, M., Qorbani, M., Arzaghi, S.M. *et al.* The mental health of healthcare workers in the COVID–19 pandemic: A systematic review. *J Diabetes Metab Disord* 19, 1967–1978 (2020). *https://doi.org/10.1007/s40200-020-00643-9.*

[246] Chen L, Birkmeyer J, Saint S, Jha A. 2013. Hospitalist Staffing and Patient Satisfaction in the National Medicare Population. Journal of Hospital Medicine, *https://doi.org/10.1002/jhm.2001.*

[247] Bacon, C.T., & Mark, B. (2009). Organizational effects on patient satisfaction in hospital medical-surgical units. The Journal of nursing administration, 39(5), 220–227. *https://doi.org/10.1097/NNA.0b013e3181a23d3f.*

[248] Aiken L, Clarke S, Sloane D. Hospital staffing, organization, and quality of care: cross-national findings. International Journal for Quality in Health Care. Int J Qual Health Care. 2002.10.1093/intqhc/14.1.5.

[249] Jeannie P. Cimiotti, et al., Nurse staffing, burnout, and health care–associated infection, American Journal of Infection Control, Volume 40, Issue 6, 2012, Pages 486–490, *https://doi.org/10.1016/j.ajic.2012.02.029* (citing Vahey DC, et al., Nurse burnout and patient satisfaction. Med Care 2004;42:II–57–66 and Leiter MP, Harvie P, Frizzell C. The correspondence of patient satisfaction and nurse burnout. Soc Sci Med 1998;47:1611–7).

[250] Aiken LH, Sloane DM, Ball J, *et al.,* Patient satisfaction with hospital care and nurses in England: an observational study, *https://bmjopen.bmj.com/content/8/1/e019189.*

[251] U.S. News, States With the Biggest Hospital Staffing Shortages (Jan. 13, 2022), *https://www.usnews.com/news/health-news/articles/2022-01-13/states-with-the-biggest-hospital-staffing-shortages* (citing data from the HHS, CDC, and

[253] Fleisher et al. (2022). ''Health Care Safety during the Pandemic and Beyond—Building a System That Ensures Resilience''. *New England Journal of Medicine.* Article available here: *https://www.nejm.org/doi/full/10.1056/NEJMp2118285?utm_source=STAT+Newsletters&utm_campaign=8933b7233e-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-8933b7233e-151759045.*

that in the absence of rigorous statistical testing we risk-adjust for COVID–19 diagnosis during an encounter. A commenter did not support suppression of the HCAHPS measure out of concern that measure suppression may worsen health inequities if performance is masked.

Response: As noted in section V.I.1.b.2 of the preamble of this final rule, we cannot risk-adjust the HCAHPS measure to exclude patients whose admissions were related to COVID–19 because this measure does not capture patient-level diagnosis data. However, we share the commenter's concern about how measure suppression may impact health equity. We believe that our proposal to continue publicly reporting suppressed measure data will provide important information that could assist in addressing health inequities caused or exacerbated by the COVID–19 PHE and maintain transparency for consumers while ensuring hospitals are not unfairly scored or penalized based on CY 2021 HCAHPS data. We note our intention to resume normal scoring for FY 2024 given the widespread availability of vaccines in CY 2022 as well advances in the treatment of COVID–19.

After consideration of the public comments we received, we are finalizing our proposal to suppress the HCAHPS measure for FY 2023 for scoring and payment purposes as proposed. We will continue to make the HCAHPS data publicly available, recognizing the importance of transparency.

(3) Suppression of the Five Healthcare-Associated Infection (HAI) Safety Measures for the FY 2023 Hospital VBP Program Year

As noted in section V.H.1.b. of the preamble of this final rule, in the FY 2022 IPPS/LTCH PPS final rule, we finalized the suppression of the five HAI Safety measures (CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) for the FY 2022 program year under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. We refer readers to the FY 2022 IPPS/LTCH PPS final rule for additional details on that policy and a summary of public comments we received related to that finalized policy (86 FR 45272 through 45274).

In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to suppress the five HAI Safety measures (CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) for the FY 2023 program year under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; and Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in healthcare personnel and patient case volumes (87 FR 28429 through 28431). We are concerned that the COVID–19 PHE affected measure performance on the HAI measures in 2021 such that we will not be able to score hospitals fairly or reliably for national comparison and payment adjustment purposes. As part of this proposal, we would calculate hospitals' five HAI measure rates, but we would not use these measure rates to generate achievement or improvement points for these measures. Additionally, because these five measures make up the entirety of the Safety domain, we would not calculate hospitals' FY 2023 Safety domain score. Participating hospitals would continue to report the measure data to the CDC and CMS so that we can monitor the effect of the circumstances on quality measurement and consider appropriate policies for the future. We would continue to provide confidential feedback reports to hospitals as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. Though we are concerned that the COVID–19 PHE has affected measure performance on the HAI measures in 2021, patient safety remains a priority in our value-based purchasing programs. Therefore, we also intend to publicly report CY 2021 data where feasible and appropriately caveated. As noted in section V.I.1.a. of the preamble of this final rule, we believe that publicly reporting suppressed measure data is an important step in providing transparency and upholding quality of care and safety for consumers.

We proposed to suppress three of the five CDC NHSN HAI measures (CLABSI, CAUTI, and MSRA bacteremia) under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45272 through 45274) for previous analysis on the HAI Safety measures that showed that measure rates for the CLABSI, CAUTI, and MRSA measures increased during the CY 2020 pandemic year as compared to the pre-COVID–19 CY 2019 year immediately preceding the COVID–19 PHE. To determine whether the CLABSI, CAUTI, and MRSA measure rates would continue to show increases for CY 2021, the CDC analyzed changes in standardized infection ratios (SIRs) for Q1 and Q2 of CY 2021 as compared to the SIRs in Q1 and Q1 of CY 2019. This analysis found that the CLASBI, CAUTI, and MSRA measures had statistically significant measure rate increases during Q1 and Q2 of CY 2021 as compared to pre-pandemic levels in Q1 and Q2 of CY 2019. For Q1 2021, the national SIR increased by approximately 45 percent for the CLABSI measure, approximately 12 percent for the CAUTI measure, and approximately 39 percent for the MRSA measure as compared to Q1 2019. For Q2 2021, the national SIR increased by approximately 15 percent for the CLABSI measure and approximately 8 percent for the MRSA measure. The SIRs for the CAUTI measure showed no statistically significant difference for Q2 2021 as compared to Q2 2019.

TABLE V.I.-02: PERCENT CHANGES IN SIRS COMPARED TO RESPECTIVE 2019 QUARTERS

	2020 Q1	2020 Q2	2020 Q3	2020 Q4	2021 Q1	2021 Q2	Preliminary 2021 Q3*
CLABSI	-11.8	27.9	46.4	47.0	45.3	14.6	48.6
CAUTI	-21.3	No change	12.7	18.8	11.5	No change	13.3
SSI: Colon surgery	-9.1	No change	-6.9	-8.3	No change	No change	-6.6
SSI: Abdominal hysterectomy	-16.0	No change	No change	-13.1	No change	No change	No change
MRSA bacteremia	-7.2	12.2	22.5	33.8	39.2	8.3	44.5%
CDI	-17.5	-10.3	-8.8	-5.5	-15.6	-14.1	-14.5%

*This data is preliminary as of the time of the FY 2023 IPPS/LTCH PPS final rule publication. The Q3 2021 HAI measure data submission deadline was February 15, 2022 and the SIR for Q3 2021 has not yet been finalized.

For the CDI measure, the national SIR decreased by approximately 16 percent for Q1 2021 as compared to Q1 2019 and by approximately 14 percent for Q2 2021 as compared to Q2 2019. The SSI measure showed no significant increase or decrease during Q1 2021 and Q2 2021 as compared to Q1 2019 and Q2 2019. Though the changes in the national SIRs for SSI and CDI were not as large as compared to the other Safety domain measures, we proposed to suppress these measures under Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in patient case volumes and Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials, respectively. Specifically, for the SSI measure, we proposed to suppress the measure for FY 2023 under Measure Suppression Factor 4, rapid or unprecedented changes in patient case volumes. We note that the SSI measure has historically had a low procedure volume for many hospitals, which impacts our ability to produce SIRs for that measure. For CY 2019, 2,087 hospitals (61 percent) did not have sufficient procedure-level data needed to calculate SSI SIRs for abdominal hysterectomy, and 1,262 hospitals (37 percent) did not have sufficient data to calculate SIRs for colon surgery. However, nationally, procedure volumes declined even further during the COVID–19 PHE in 2020, compared to 2019, with decreases of up to 23 percent for colon procedures and 39 percent for abdominal hysterectomy procedures.[254] As of July 2021, abdominal hysterectomy procedures were still 6 percent below predicted levels.[255] These changes in patient volumes for the SSI measure limit our ability to calculate SSI SIRs for hospitals that do not have sufficient data in FY 2023, which may impact the accuracy and reliability of overall national comparison on performance for this measure.

For the CDI measure, we proposed to suppress the measure under Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, related protocols, or equipment or diagnostic tools or materials. Pandemic-related improvements to typical CDI prevention practices such as hand hygiene, PPE practices, and environmental cleaning could have contributed to the declines seen in the CDI SIR in 2021 compared to 2019.[256] In addition, a decline in outpatient antibiotic prescribing was observed starting in 2020 as healthcare utilization decreased during the COVID–19 pandemic.[257] This, combined with the continued use of inpatient antibiotic stewardship programs in hospitals, may also have contributed to the decline in the national CDI SIRs, as reducing patient antibiotic exposure is a recommended strategy for CDI prevention. More information about CDI prevention strategies can be found at *https://www.cdc.gov/cdiff/clinicians/cdi-prevention-strategies.html.*

Additionally, because we cannot identify all potential elements that could be impacting the overall HAI experience at facilities during an unprecedented PHE as well as potential geographic disparities in the impact of the PHE that could cause uneven impact on facilities based on their location, and in order to reduce bias toward only those measures that are performing well at the national level, we believe all five CDC NHSN HAI measures should be suppressed. Therefore, we believe it is appropriate to suppress all five HAI measures in the Safety domain to ensure an accurate and reliable national comparison of performance on hospital safety.

We also proposed to suppress the five CDC NHSN HAI measures for the FY 2023 program year under Measure Suppression Factor 4, significant national shortage or rapid or unprecedented changes in healthcare personnel. As discussed in section V.I.1.b.(2). Of the preamble of this final rule, during the course of the COVID–19 PHE, an unprecedented number of healthcare personnel have left the workforce or ended their employment in hospitals.[258] This healthcare personnel shortage worsened in 2021, with hospitals across the United States reporting 296,466 days of critical staffing shortages, an increase of 86 percent from the 159,320 days of critical staffing shortage hospitals reported in 2020.[259] Healthcare workers, especially those in areas with higher infection rates, have reported serious

[254] Weiner-Lastinger, L, et al,. The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology (2022), 43, 12–25. doi:10.1017/ice.2021.362.

[255] *https://epicresearch.org/articles/elective-surgeries-approach-pre-pandemic-volumes.*

[256] Weiner-Lastinger LM, et al. (2021). The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology, *https://doi.org/10.1017/ice.2021.362.*

[257] The intersection of antibiotic resistance (AR), antibiotic use (AU), and COVID–19. Department of Health and Human Services website. *https://www.hhs.gov/sites/default/files/antibiotic-resistance-antibiotic-use-covid-19-paccarb.pdf.* Published February 10, 2021. Accessed June 28, 2021.

[258] Health Affairs, *COVID–19's Impact on Nursing Shortages, The Rise of Travel Nurses, and Price Gouging* (Jan. 28, 2022), *https://www.healthaffairs.org/do/10.1377/forefront.20220125.695159/.*

[259] *https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/g62h-syeh.*

psychological symptoms, including anxiety, depression, and burnout.[260] [261]

Healthcare personnel staffing shortages and burnout has been shown to be significantly associated with hospital-associated infections, including urinary tract infections and surgical site infections.[262] [263] Along with being shown to impact quality of care,[264] healthcare staffing shortages impact a hospital's ability to investigate infections and take corrective action.[265] As discussed in section V.I.1.b.(2). Of the preamble of this final rule, reports of hospital staff shortages have varied widely geographically, ranging from 10 to 50 percent of hospitals in any particular state reporting staffing shortages. Given the wide variance in reported staffing shortages, and the impact staffing shortages may have on CDC NHSN HAI scores, we believe our proposal to suppress the CDC NHSN HAI measures fairly addresses the geographic disparity in the impact of the COVID–19 PHE on participating hospitals.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45272 through 45274), we stated our belief that the distortion in measure performance may be due to circumstances unique to the effects of the pandemic such as staffing shortages and turnover, patients that are more susceptible to infections due to increased hospitalization stays, and longer indwelling catheters and central lines. We believe that the continued distortion in measure performance is impacted by similar circumstances unique to the effects of the COVID–19 PHE as hospitals and researchers have investigated the impact of COVID–19 on HAIs and found that COVID–19 is associated with increases in HAIs, with changes in the SIR varying geographically and over time.[266] [267] [268] [269] [270] Additionally, we believe that suppressing the HAI measures is appropriate because the impact of COVID–19 on the measure cannot be addressed through risk-adjustment. Under current collection requirements for the CDC NHSN HAI measures, the data used for risk adjustment are collected at the ward or facility level, meaning that the hospital submits infection data for a given ward or the entire facility rather than at the individual patient level. Accordingly, we are not able to identify the number of patients with HAIs who also had COVID–19 and therefore cannot risk-adjust for or otherwise account for COVID–19 diagnoses. In order to address the impact of the ongoing COVID–19 PHE on HAI incidence, we proposed to suppress the CY 2021 HAI measure data.

We welcomed public comment on our proposal to suppress the five HAI Safety domain measures for the FY 2023 program year for purposes of scoring and payment.

Comment: Many commenters supported suppression of the HAI measures and expressed appreciation that suppression would ensure that hospitals are not penalized for challenges brought on by the pandemic which are not representative of the care generally provided.

Response: We thank the commenters for their support of the HAI measure suppression proposals and we agree that suppressing these measures for scoring and payment purposes will ensure that hospitals are not penalized for impacts outside of their control.

Comment: A few commenters recommended we continue analyzing data to determine whether suppressions may be necessary in future fiscal years. A commenter also recommended careful reintroduction of the measures at an appropriate time.

Response: We thank the commenters for their recommendations, and we will continue to monitor the COVID–19 PHE's ongoing effects. As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28433) and section V.I.2 of this final rule, we believe that 2022 has a more promising outlook in the fight against COVID–19 as we enter the third year of the pandemic. Our goal is to resume the use of measure data for scoring and payment adjustment purposes beginning with the FY 2024 program year, given the widespread availability of vaccines and improvement in the treatment of COVID–19, but we will continue to analyze data.

Comment: A commenter supported hospitals continuing to report the measure data to CDC and CMS to ensure ongoing quality improvement monitoring and further recommended that we use those data to assess whether variability in reporting (for example due to relief extended to providers during implicated COVID–19 reporting periods) versus variability in actual performance could be driving variability in HAI rates.

Response: We appreciate the commenter's recommendation and agree that it is essential that hospitals continue to report data. The FY 2023 program year uses data from CY 2021 for the HAI measures. There were no widespread data submission exceptions in CY 2021 like there were for Q1 and Q2 of 2020 (85 FR 54820).[271] Therefore, we believe our analysis of CY 2021 data shows actual variability in performance. With that noted, the COVID–19 PHE has caused a variety of factors to impact hospital performance on the HAI measures, including but not limited to wide variation in case rates by geographic area at different points in time. Therefore, we believe the best

[260] Kriti Prasad, Colleen McLoughlin, Martin Stillman, Sara Poplau, Elizabeth Goelz, Sam Taylor, Nancy Nankivil, Roger Brown, Mark Linzer, Kyra Cappelucci, Michael Barbouche, Christine A. Sinsky. Prevalence and correlates of stress and burnout among U.S. healthcare workers during the COVID–19 pandemic: A national cross-sectional survey study. EClinicalMedicine, Volume 35. 2021. 100879. ISSN 2589–5370. *https://doi.org/10.1016/j.eclinm.2021.100879*.

[261] Vizheh, M., Qorbani, M., Arzaghi, S.M. *et al.* The mental health of healthcare workers in the COVID–19 pandemic: A systematic review. *J Diabetes Metab Disord* 19, 1967–1978 (2020). *https://doi.org/10.1007/s40200-020-00643-9*.

[262] Jeannie P. Cimiotti, et al., Nurse staffing, burnout, and health care-associated infection, American Journal of Infection Control, Volume 40, Issue 6, 2012, Pages 486–490, *https://doi.org/10.1016/j.ajic.2012.02.029*.

[263] Jinjin Shang, et al., Nurse staffing and Healthcare Associated Infection, Unit-level Analysis, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6478399/*.

[264] Aiken L., Clarke S., Sloane D. Hospital staffing, organization, and quality of care: cross-national findings. International Journal for Quality in Health Care. Int J Qual Health Care. 2002.10.1093/intqhc/14.1.5.

[265] Healthcare-Associated Infections Increase Dramatically During Pandemic, *https://www.reliasmedia.com/articles/148560-healthcare-associated-infections-increase-dramatically-during-pandemic*.

[266] Fakih M.G., et al. (2021). Coronavirus disease 2019 (COVID–19) pandemic, central-line-associated bloodstream infection (CLABSI), and catheter-associated urinary tract infection (CAUTI): The urgent need to refocus on hardwiring prevention efforts. Infection Control & Hospital Epidemiology, *https://doi.org/10.1017/ice.2021.70*.

[267] Palmore T.N. and Henderson D.K. (2021). Healthcare-associated infections during the coronavirus disease 2019 (COVID–19) pandemic. Infection Control & Hospital Epidemiology, *https://doi.org/10.1017/ice.2021.377*.

[268] Weiner-Lastinger L.M., et al. (2021). The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology, *https://doi.org/10.1017/ice.2021.362*.

[269] Baker, Meghan A. et al. ''The Impact of COVID–19 on Healthcare-Associated Infections.'' Clinical infectious diseases: an official publication of the Infectious Diseases Society of America, ciab688. 9 Aug. 2021, doi:10.1093/cid/ciab688.

[270] Advani, Sonali D. et al. ''The impact of coronavirus disease 2019 (COVID–19) response on hospital infection prevention programs and practices in the southeastern United States.'' Infection control and hospital epidemiology, 1–4. 2 Nov. 2021, doi:10.1017/ice.2021.460.

[271] Centers for Medicare and Medicaid Services. (2020). CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19. Available at: *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting*.

approach for the FY 2023 Hospital VBP Program is measure suppression for purposes of scoring and payment. However, in collaboration with the CDC, we will continue to collect, monitor, and analyze the HAI data, as well as continue publicly reporting the data with appropriate caveats as necessary.

Comment: Several commenters did not support suppression of the HAI measures, stating their belief that hospitals should be held accountable for their quality of care. A commenter did not support suppression of infection rates because of concerns around transparency.

Response: As discussed in section V.I.1.a of this final rule, although we are finalizing our proposals to suppress the HAI measures for the purposes of scoring and payment adjustments for the FY 2023 program year, we are also finalizing that we will make the data publicly available, recognizing the importance of transparency. We believe that continuing to make the data publicly available ensures transparency for consumers as they decide where to obtain care. We will also continue to provide confidential feedback reports to hospitals through the previously established processes as part of program activities to ensure that hospitals are made aware of the changes in performance rates that we observe and to inform their quality improvement activities.

Comment: A commenter did not support suppressing entire data and reporting periods, noting concerns about the consequences of widespread suppression and that, in the absence of rigorous statistical testing, instead recommended we risk-adjust for COVID–19 diagnosis during an encounter.

Response: We appreciate the recommendation to risk adjust for COVID–19 diagnosis, but we cannot risk adjust the HAI measures to exclude patients whose admissions were related to COVID–19 because the HAI measures do not capture patient-level diagnosis data. Additionally, we believe the HAI rates would still be impacted even with COVID–19 risk adjustment because the PHE has affected hospital staffing and resource issues which impact a hospital's entire patient population, regardless of a COVID–19 diagnosis.

Comment: A commenter did not support suppressing HAI measures because of the belief that it weakens hospitals' resilience, given that the Measure Suppression Factors justify suppression for a wide variety of environmental shifts, including changes in national performance, guidelines, and case mix. The commenter holds the belief that suppressing payment incentive programs when the environment shifts does not strengthen hospital resilience.

Response: We agree that building a more resilient health care system is necessary to avoid future threats to patient safety.[272] However, we also believe that suppressing the HAI measures for purposes of scoring and payment for FY 2023 balances the need to provide hospitals with the flexibility to focus on delivery of care without penalizing them for the changing conditions of the COVID–19 PHE during the 2021 performance period that were beyond hospitals' control and to maintain access to care for patients. As we noted previously, our goal is to resume the use of measure data for scoring and payment adjustment purposes beginning with the FY 2024 program year.

Comment: A commenter did not support the HAI suppression proposal and expressed concern about the Measure Suppression Factors lacking sufficient definition, and thus transparency, thereby suppressing critically important data on hospital-acquired infection measures. A commenter did not support HAI suppression because it was concerned about CMS adhering to, interpreting, and operationalizing the Measure Suppression Factors given that an ever-changing landscape can be tied to most measures.

Response: We appreciate the commenter's concern regarding the definitions of the Measure Suppression Factors. We note that the Measure Suppression Factors we are employing to suppress the HAI measures for FY 2023 in this final rule were finalized in the FY 2022 IPPS/LTCH PPS final rule, and we did not propose any changes to those Measure Suppression Factors in the FY 2023 IPPS/LTCH PPS proposed rule (86 FR 45266 through 45269). We also note that these Measure Suppression Factors were developed to specifically address challenges that arose due to the COVID–19 PHE, and we considered what circumstances caused by the COVID–19 PHE would affect a quality measure significantly enough to warrant its suppression in the Hospital VBP Program. Although the landscape is ever-changing, the COVID–19 PHE presented unique and unprecedented experiences that challenged hospitals in new ways beyond their control, particularly in 2020 when the virus was initially identified as a global pandemic and then in 2021 as new COVID–19 variants increased infection rates to higher levels than 2020 for many parts of the U.S. Due to these unique challenges, we believe that it would be unfair to score or penalize hospitals based on CY 2021 data for the HAI measures. We note our intention to resume normal scoring for FY 2024 given the widespread availability of vaccines in CY 2022 as well advances in the treatment of COVID–19.

Comment: A commenter did not support HAI suppression because of the belief that being unable to determine the causes of changes in HAI rates is not a rationale for suppression. The commenter stated that, in light of the numerous factors that can potentially impact improvement on a given HAI or other outcome of interest, the commenter believes that CMS is focusing too much on the statistical analysis rather than protecting the lives and health of Medicare beneficiaries and the public at large. The commenter questioned whether these statistical analysis concerns could be used to suppress virtually all measures in virtually all circumstances. A commenter did not support HAI suppression because of the belief that the rationale exceeds CMS authority and recommended CMS retract its stated rationale for the suppression of NHSN CDC HAIs in the FY 2022 IPPS/LTCH PPS final rule.

Response: We believe that, in the face of evolving circumstances of the COVID–19 PHE, the level of detail in the Measure Suppression Factors, which were developed and finalized in the FY 2022 IPPS/LTCH PPS final rule to specifically address challenges that arose due to the COVID–19 PHE, is sufficient and applicable in suppressing the HAI measures. In deciding which measures to suppress, and as discussed in the proposed rule and this final rule, we examined each measure and determined that the evidence showed significant deviation in the individual measure's performance data associated with the COVID–19 PHE. We believe hospitals' experiences during the COVID–19 PHE in 2021 with the rise of new COVID–19 variants have been uniquely challenging, thus warranting the use of Measure Suppression Factors. We note our measure-by-measure assessment in determining the impacts of COVID–19 on each measure and whether we should propose to suppress a measure for scoring and payment

[272] Fleisher et al. (2022). ''Health Care Safety during the Pandemic and Beyond—Building a System That Ensures Resilience''. *New England Journal of Medicine.* Available at: *https://www.nejm.org/doi/full/10.1056/NEJMp2118285?utm_source=STAT+Newsletters&utm_campaign=8933b7233e-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-8933b7233e-151759045.*

purposes in a pay-for-performance program or not. Ultimately, we determined to propose to suppress the HCAHPS and HAI measures for FY 2023 scoring and payment purposes as discussed previously, but we did not propose to suppress the Medicare Spending per Beneficiary or Clinical Outcome measures (mortality and complications), especially if there were technical refinements that could be made to address COVID–19 impacts on a measure.

Comment: A commenter did not support HAI measure suppression because of a concern that suppression policies may worsen health inequities.

Response: We are committed to addressing health inequities, and we believe that our continued requirements for the collection and reporting by hospitals of the HAI data to CMS via the CDC's National Healthcare Safety Network and proposal that we are finalizing to publicly report the FY 2023 program year HAI measure data will provide important performance information that could assist in addressing health inequities caused by the COVID–19 PHE while maintaining transparency for consumers and ensuring hospitals are not unfairly scored or penalized. We also believe that suppressing the HAI measures for purposes of scoring and payment for FY 2023 balances the need to provide hospitals with the flexibility to focus on delivery of care without penalizing them for the changing conditions of the COVID–19 PHE during the 2021 performance period that were beyond hospitals' control and to maintain access to care for patients. We note that it is our intent to resume normal scoring for FY 2024 given the widespread availability of vaccines in CY 2022 as well advances in the treatment of COVID–19.

Comment: A commenter expressed concern over inconsistency in the citation of Measure Suppression Factors across the HAC Reduction Program and the Hospital VBP Program for the same measures, noting that it appeared to be an uneven application of the Measure Suppression Factor policy. The commenter recommended we find ways to adapt the Measure Suppression Factor policy across the programs in order to use the critical safety measures discussed in transparency and value-based purchasing.

Response: We appreciate the commenter's concern regarding consistency. We believe that the Measure Suppression Factors which were applied for the same set of HAI measures used in the Hospital VBP Program and the HAC Reduction Program are relevant and aligned across both programs. We continue to believe that suppressing the HAI measures for purposes of FY 2023 scoring and payment under both the Hospital VBP Program and the HAC Reduction Program will continue to provide flexibility for providers to focus on delivering quality of care to patients during the COVID–19 PHE.

After consideration of the public comments we received, we are finalizing our proposal to suppress the HAI measures for purposes of scoring and payment for FY 2023 as proposed. We will continue to make the HAI data publicly available, recognizing the importance of transparency.

c. Scoring and Payment Methodology for the FY 2023 Program Year Due to the COVID–19 PHE

As described in section V.I.1.b. of the preamble of this final rule, we proposed to suppress six measures in the Hospital VBP Program for FY 2023 and use a special rule for FY 2023 scoring, which we would codify in our regulations at 42 CFR 412.168. Specifically, we proposed that we would calculate measure rates for all measures in the FY 2023 program year. For measures for which we have finalized suppression, we will not use the measure rates to generate achievement and improvement points within the Hospital VBP Program's current scoring methodology. We further proposed under this special rule that we would only calculate achievement and improvement points, as well as a domain score, for remaining measures in the Clinical Outcomes domain and the Efficiency and Cost Reduction domain that have not been proposed for suppression and that, because no other domains receive scores for the FY 2023 program year, we would not award TPSs to any hospital for FY 2023.

Because no hospital would receive a TPS for FY 2023, we will reduce each hospital's base-operating DRG payment amount by two percent, as required under section 1886(o)(7)(B) of the Act, and then assign to each hospital a value-based incentive payment amount that matches the two percent reduction to the base operating DRG payment amount. The net result of these payment adjustments will be neutral for hospitals. We have stated that value-based payment systems should rely on a mix of standards, processes, outcomes, and patient experience measures (76 FR 26491). As such, the Hospital VBP Program scoring methodology was developed to be used with several measures across multiple domains and aims to score hospitals on their overall achievement relative to national benchmarks. Unlike other hospital value-based purchasing programs that are intentionally designed to focus on specific aspects of quality, such as the HAC Reduction Program and the Hospital Readmissions Reduction Program, the Hospital VBP Program is uniquely designed to address a comprehensive set of quality and efficient metrics that evaluate multiple facets of quality. However, as discussed in the measure suppression proposals in section V.I.1.b. of the preamble of this final rule, the data from several measures has been significantly impacted by the COVID–19 PHE. Awarding negative or positive incentive payment adjustment percentages using TPSs calculated using the current scoring methodology would not provide a representative score of a hospitals' overall performance in providing quality of care during a pandemic. We believe that the current scoring methodology remains a balanced and comprehensive approach for tying payment to hospitals for their performance on a set of diverse measures that depict quality of care provided. However, we understand that the COVID–19 PHE has led to sudden and unexpected changes to healthcare systems. Our measure suppression policy was designed as a non-permanent approach to provide flexibility for changing conditions outside of participating hospitals' control and to avoid penalizing hospitals on measure scores that we believe are distorted by the COVID–19 PHE and are thus not truly reflective of quality of care. As we enter the third year of the pandemic, we believe that the updated knowledge of the virus and access to various treatment and mitigation efforts in place have provided hospitals with various tools to adapt to this virus. Therefore, as we discuss further in section V.I.2. of the preamble of this final rule, our goal is to continue resuming the use of measure data for scoring and payment adjustment purposes beginning with the FY 2024 program year.

In order to ensure that hospitals are aware of changes in their performance rates that we have observed, in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to provide FY 2023 confidential feedback reports that contain the measure rates we have calculated for the FY 2023 program year, along with achievement and improvement scores for all the measures in the Cost and Efficiency Reduction domain and the Clinical Outcomes domain that have not been finalized for suppression and a Cost and Efficiency

Reduction domain and a Clinical Outcomes domain score (87 FR 28431 through 28434). However, as previously discussed, we would not calculate TPSs for the purpose of adjusting hospital payments under the FY 2023 Hospital VBP Program. We note that the proposed special scoring methodology for FY 2023 generally aligns with the special scoring methodology finalized in for FY 2022 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45295 through 45296).

In the proposed rule, we also stated our understanding that, if finalized, the FY 2023 special scoring and payment policy proposal for the Hospital VBP Program would have implications for the Merit-Based Incentive Payment System (MIPS) program (87 FR 28432). Under the facility-based measurement option within MIPS described at 42 CFR 414.1380I, clinicians eligible for facility-based measurement may have their MIPS quality and cost performance category scores based on the Total Performance Score of the applicable hospital from the Hospital VBP Program as determined under 42 CFR 414.1380(e)(5). As described at 42 CFR 414.1380(e)(1)(ii) and in the CY 2019 PFS final rule, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period. Thus, for the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the Total Performance Score under the Hospital VBP Program for the FY 2023 program year would be applied. If a hospital does not have a Total Performance Score under the Hospital VBP Program for FY 2023, facility-based measurement would not be available for the MIPS eligible clinicians to whom that hospital's Total Performance Score would be applicable. If our proposed special scoring policy for the Hospital VBP Program for FY 2023 is finalized, hospitals would not have a FY 2023 Total Performance Score, and the clinicians who would normally be assessed through facility-based measurement would need to identify another method of participating in MIPS for the CY 2022 MIPS performance period/CY 2024 MIPS payment year or submit an application for reweighting a performance category or categories, if applicable.

We invited public comment on these proposals.

Comment: Many commenters supported our proposed scoring and payment methodology for the FY 2023 program year. Commenters noted that they believe our approach is proactive and noted that this policy will help ensure providers are not penalized for impacts outside of their control. Commenters also expressed appreciation that we are accounting for the on-going effects of the COVID–19 PHE in hospitals. A commenter noted that they believe we struck the right balance by ensuring transparency of quality performance data, while at the same time, not penalizing hospitals when their performance scores are highly related to the COVID–19 PHE. A few commenters thanked us for recognizing that COVID–19 has significantly impacted quality measures and expressed support for our efforts to prevent skewed payment incentives and inequitable payments in the Hospital VBP Program. Commenters also expressed appreciation for our engagement with hospitals to gauge the impact of COVID–19 on individual measures and programs, and for using a data-driven approach to inform proposals. A few commenters noted that this proposed policy would provide important relief and stability for providers, especially rural providers, regarding compliance concerns so they can focus on the unique challenges of providing care during the COVID–19 PHE.

Response: We thank commenters for their support, and we agree that the policy will help ensure that providers are not penalized for impacts outside of their control. We also agree that our proposed suppression, scoring, and payment policies for the FY 2023 program year were developed using data-driven approaches and are intended to balance the importance of patient safety through data collection, transparency, and public reporting while allowing hospitals to focus on maintaining access and providing quality health care to patients during the COVID–19 PHE.

Comment: Several commenters urged us to continue to carefully review the impact of the COVID–19 PHE and revised technical specifications on measure performance prior to establishing a policy for Hospital VBP Program payment adjustments in future years. A commenter encouraged us to resume full implementation of hospital quality programs as soon as reliable data are available for evaluating hospital performance because the measures used in those programs are intended to promote improvements in critical patient safety and quality of care. A few commenters also encouraged us to engage interested parties in developing a permanent suppression policy that could be used for future PHEs and to include lessons learned from the COVID–19 PHE. A commenter urged us to continue the suppression policy through the end of the PHE and noted their belief that data through at least Q2 2022 should not be used to inform penalties under any of the quality programs. A commenter recommended we ignore all data from CY 2020 and CY 2021.

Response: We thank commenters for these suggestions. We note that the current measure suppression policy, as finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45266 through 45269), has been adopted for the duration of the COVID–19 PHE. Therefore, we may continue to propose to suppress measures through the end of the COVID–19 PHE if we determine that the Measure Suppression Factor criteria have been met and that quality measure data continue to be significantly impacted by the COVID–19 PHE. We note that we did not want to take a blanket approach to the suppression of CY 2020 or CY 2021 data and instead have analyzed CY 2020 and CY 2021 data on a measure-by-measure basis for the measures used in the Hospital VBP Program, and have finalized specific policies based on the data and technical specifications for each particular measure (such as specific measure suppressions and updated baseline periods) to appropriately address any COVID–19 impacted data from those time periods. For example, for certain measures we determined that the data did not warrant proposing to suppress for FY 2023, such as the Medicare Spending per Beneficiary measure.

Comment: Many commenters expressed support for providing suppressed measure data on hospital performance in hospital confidential feedback reports. Commenters noted that it is helpful to continue receiving these reports with measure rates, which allows hospitals to analyze their performance and continue focusing on performance improvements.

Response: We thank commenters for their support and agree that providing hospitals with information related to measure rates for suppressed measures can be a useful tool in evaluating and improving quality of care provided. We will continue to provide confidential reporting of all measures, including those that are suppressed from scoring calculations, via the Payment Percentage Summary Report (PPSR), though we will not calculate domain or Total Performance Scores. Providing confidential measure results to hospitals also serves as an opportunity to preview the data before they are publicly

reported on the Compare tool hosted by HHS.

Comment: Several commenters supported publicly reporting suppressed measure data. A few commenters noted that it is important for the public to have access to key hospital safety data. A commenter noted that timely, accurate, comprehensive, and clear public reporting of quality measure data is meaningful for patients. Commenters encouraged us to include information on the Care Compare website explaining the appropriate use and interpretation of the publicly reported data so that others, who might intend to use the data for other purposes, also can consider whether their intended use needs to be adjusted or suppressed for a time period due to COVID–19 impacts.

Response: We appreciate commenters' support and agree that it is important for the public to have access to Hospital VBP Program data through resources such as the Compare tool to continue to make informed health care decisions. As noted in the preamble of the final rule and proposed rule, we intend to publicly report suppressed data with appropriate caveats that explain that performance information has been impacted due to the COVID–19 PHE.

Comment: A few commenters expressed concern with the proposed scoring methodology for the FY 2023 program year because of the implications it would have for the Medicare Incentive Payment System (MIPS) Program for eligible clinicians. Specifically, commenters were concerned that clinicians eligible for facility-based measurement will not be able to base their MIPS quality and cost performance category scores on the Total Performance Score of the applicable hospital from the Hospital VBP Program if we finalize the special scoring methodology for FY 2023 as proposed. A commenter noted that some clinicians may not have the resources or technology to report quality measures through an electronic health record, registry, or quality clinical data registry (QCDR) and suggested that we award TPSs for FY 2023, use TPSs from prior years, or create a hold harmless provision to ensure that hospital-based clinicians are not penalized and do not receive a downward payment adjustment under the MIPS Program. A commenter requested that we align the scoring and payment policies between the Hospital VBP Program and the MIPS Programs such that facility-based providers would receive net neutral payment adjustments under the MIPS program as well. Another commenter suggested that we offer an automatic Extreme and Uncontrollable Circumstances (EUC) exception to facility-based providers for FY 2022 to avoid impacting their cost and quality scores under MIPS.

Response: We understand commenters' concerns around the implications the special scoring methodology for FY 2023 under the Hospital VBP Program would have for clinicians under MIPS. However, because no hospitals will have a FY 2023 Total Performance Score, the clinicians who are normally assessed through facility-based measurement will need to identify another method of participating in MIPS for the CY 2022 MIPS performance period/CY 2024 MIPS payment year or submit an EUC application [273] to request the reweighting of one or more performance categories, if applicable. With regard to the commenter's suggestion that we award TPSs for FY 2023 or use TPSs from prior years, we do not believe it would be an appropriate or meaningful indication of quality to award hospitals TPSs under the Hospital VBP Program based only on the unsuppressed measures in the Efficiency and Cost Reduction and the Clinical Outcomes domains for the FY 2023 program year because we do not believe it would result in nationally comparable assessment of quality of care for overall hospital performance without the inclusion of the suppressed measures. Further, we believe that awarding TPSs under the Hospital VBP Program from prior years would not be useful, equitable, or meaningful as it would not be new information and could potentially cause confusion for some hospitals around their actual performance during the COVID–19 PHE as it would be re-using data from prior to the COVID–19 PHE. Additionally, any changes to the previously established policies for MIPS, such as commenters' suggestions to create a hold harmless provision to ensure that hospital-based clinicians are not penalized and do not receive a downward payment adjustment under the MIPS Program or to offer an automatic EUC exception, would be determined by and communicated through the appropriate channels for MIPS.

Comment: Some commenters did not support the proposed payment methodology for the FY 2023 program year. A commenter expressed concern that the proposed special payment policy for FY 2023 that would result in net neutral payments for hospitals does not recognize investments in and on-going costs of quality infrastructure made by hospitals that maintained strong performance on measures prior to the COVID–19 pandemic. This commenter suggested that we consider establishing alternate performance periods, such as CY 2019 or a blend of prior performance periods, in order to score hospitals for the FY 2023 program year. A few commenters requested that we explore the authority to allow payment adjustments for hospitals that would have earned a positive payment adjustment for the FY 2023 program to reward hospitals that have demonstrated positive performance under the Hospital VBP Program throughout the COVID–19 PHE.

Response: We recognize that many hospitals have made important investments in infrastructure and processes to improve quality of care both before the COVID–19 PHE and during the PHE, and we encourage hospitals to continue investing in quality infrastructure that improves delivery of care. care. Though we recognize that some hospitals have maintained strong performance on measures throughout the COVID–19 PHE, we believe COVID–19 has interfered with the ability to accurately compare measure performance of hospitals side-by-side on a national level due to the variation in the impacts of the COVID–19 PHE in 2021 across time and across geographies, and whether that performance was positive or negative. Additionally, to reward hospitals that have improved quality of care during the PHE would require penalizing hospitals with negative payment adjustments based on measure scores, which we believe to be inappropriate given that we believe these scores are distorted by the COVID–19 PHE during 2021 and, thus, not reflective of the quality of care that the measures in the Hospital VBP Program were designed to assess. As noted previously in this section, we believe that awarding TPSs to hospitals based on prior performance periods would not be useful or meaningful as it would not be new information and could potentially cause confusion for some hospitals around their actual performance during the COVID–19 PHE as it would be re-using data from prior to the COVID–19 PHE. However, the measure data will continue to be publicly reported, which will provide transparency regarding performance during the COVID–19 PHE.

Comment: Several commenters expressed opposition to suppressing measure data from public reporting. A commenter noted that it was firmly

[273] EUC Application available at: *https://qpp.cms.gov/mips/exception-applications.*

against eliminating the reporting of patient safety measures, including HAI and mortality rates, because they are crucial to performance comparisons across healthcare facilities. A few commenters expressed that suppressing measure data from the public would thwart the public's ability to evaluate the strength and resilience of the health care system and make informed decisions regarding health care and public policy. A commenter expressed their belief that the public has a right to know hospital infection rates and other complication rates for hospitals receiving federal funding, regardless of the impact of the COVID–19 PHE. A few commenters noted that the suppressed measure data are important to keep public and could be used to inform future improvements in delivery of care.

Response: We agree with commenters that hospitals should continue collecting and reporting suppressed measure data and that we should continue publicly reporting suppressed measure data, and we will continue to do so under the policy we are finalizing for the FY 2023 program year. As noted in section V.I.1.a. of the preamble of this final rule, we believe that publicly reporting suppressed measure data is an important step in providing transparency.

Comment: Several commenters did not support our proposal to continue publicly reporting suppressed measure data. A commenter noted its belief that the general public does not understand the complex methodology behind the publicly posted data, and the uneven impacts of the COVID–19 PHE across geographical area might further skew how the public interprets the measure data. This commenter also noted that enterprising organizations might continue to use the publicly reported data without considering the effects of the COVID–19 PHE on that data and unfairly penalize hospitals. Several commenters noted that displaying suppressed measure data will have limited value and would likely cause confusion or misinterpretation of quality, even with caveats attached. A few commenters suggested that we provide hospitals with the option to opt-in to public reporting as part of their confidential feedback review. A commenter noted that publicly reporting data is an additional stressor that detracts from hospitals focusing on other priority areas during the COVID–19 PHE. A commenter expressed its belief that interested parties should have the opportunity to provide public comments on the public reporting determination in any future suppression policies.

Response: We understand commenters' concerns with publicly reporting suppressed measure data. However, we disagree that publicly reporting suppressed measure data is not useful for interested parties. We continue to place significant value on being as transparent as possible with the data we collect, and we will make clear with caveats that performance data were affected by the COVID–19 PHE, which impacts occurred in different ways and at different times of the year that we believe impact their national comparability for payment purposes. However, we believe the measures themselves remain reliable and useful for quality improvement purposes. Further, we disagree with the suggestion to allow hospitals the option to opt-in to public reporting. We believe that hospitals would choose to opt-in based on how well they performed, which could cause confusion, distorting the data and providing an incomplete picture of the impact of COVID–19 on performance. We acknowledge there may be limitations of these data, but believe this policy will balance our responsibility to provide transparency to consumers while ensuring that hospitals are not unfairly scored or penalized through FY 2023 payment. We encourage hospitals to continue focusing on providing quality care, using any insight they might gain from their measure rates to inform their own priority areas for improvement.

Comment: A commenter urged us to consider the implications of exempting quarters of data from reporting on measure reliability and accuracy in future public reporting. This commenter urged us to perform measure reliability analyses, using shortened performance periods to ensure CMS has sufficient data to calculate performance accurately, and to make public the results of those analyses.

Response: We thank the commenter for their feedback, and we wish to clarify that we have not proposed to exempt any quarters of measure data or to shorten performance periods for any measures from current or future reporting under the Hospital VBP Program in this rule beyond the exception for Q1 and Q2 of 2020 (85 FR 54820).[274] The only measures still affected by the nationwide COVID–19 related Extraordinary Circumstances Exception (ECE) that CMS issued in March 2020 are the mortality and complications measures. These measures use a 36-month performance period, and our analyses show these measures continue to perform with good reliability even when calculated with 30 months of data. We agree that reporting reliable and accurate data are important, and any future policies that might impact measure reliability and accuracy would be accompanied by relevant and comprehensive analyses.

After consideration of the public comments we received, we are finalizing the scoring and payment methodology for the FY 2023 program year as proposed.

2. FY 2023 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and we refer readers to that rule for further details. We note that in section V.I.1.b. of the preamble of this final rule, we are finalizing our proposal to suppress several measures in the Hospital VBP Program for the FY 2023 program year, and in section V.I.1.c. of the preamble of this final rule, we are finalizing our proposal to apply special scoring and payment adjustment policies for the FY 2023 program year. Because we are finalizing these policies, each hospital will receive the payment reduction for the Hospital VBP Program as required by statute, but every hospital will receive a value-based incentive payment amount that matches the payment reduction amount.

In the FY 2023 IPPS/LTCH PPS proposed rule, we stated that if our proposals to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount are finalized, we would not update Table 16 as Table 16A in the final rule. We stated in the FY 2023 IPPS/LTCH PPS proposed rule that if our proposals to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount are finalized, we would also not post Table 16B (which

[274] Centers for Medicare and Medicaid Services. (2020). CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19. Available at: *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

we typically do to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the applicable program year, after hospitals have been given an opportunity to review and correct their actual TPSs). Because we are finalizing our proposed measure suppression and scoring and payment policies in response to the COVID–19 PHE, we will not post a Table 16A or a Table 16B.

We continue to be concerned about the impact of the COVID–19 PHE, but we also remain encouraged by the rollout of COVID–19 vaccinations to more age groups and new antiviral treatments for those diagnosed with COVID–19. We also believe that hospitals are better prepared to treat patients with COVID–19 than they were two years ago. Our measure suppression policy focuses on a short-term, equitable approach during this unprecedented PHE, and was not intended for indefinite application. Additionally, we want to emphasize the long-term importance of value-based care and incentivizing quality care tied to payment. The Hospital VBP Program is an example of our long-standing effort to link payments to healthcare quality in the inpatient hospital setting.[275]

We understand that the COVID–19 PHE is ongoing and unpredictable in nature, however, we believe that 2022 has a more promising outlook in the fight against COVID–19. As we enter the third year of the pandemic, healthcare providers have gained experience managing the disease, surges of COVID–19 infection, and adjusting to supply chain fluctuations.[276] In 2022 and the upcoming years, we anticipate continued availability and increased uptake in the use of vaccinations,[277] including the availability and use of vaccination for young children ages 5–11, who were not eligible for vaccination for the majority of 2021 and for whom only 36 percent had received at least one dose as of June 29, 2022.[278] [279] On June 17, 2022, the Food and Drug Administration (FDA) also authorized emergency use of the COVID–19 vaccine for children as young as 6 months old, which has opened up eligibility to 18 million children.[280] [281]

Additionally, the FDA has expanded availability of at-home COVID–19 treatment, having issued the first emergency use authorizations (EUAs) for two oral antiviral drugs for the treatment of COVID–19 in December 2021.[282] [283] Finally, the Biden-Harris Administration has mobilized efforts to distribute home test kits,[284] N–95 masks,[285] and increase COVID–19 testing in schools,[286] providing more treatment and testing to the American people. Therefore, we note that our goal is to continue resuming the use of measure data for scoring and payment adjustment purposes beginning with the FY 2024 program year. That is, for FY 2024, for each hospital, we would plan to calculate measure scores for the measures in the Hospital VBP Program for which the hospital reports the minimum measure requirements, as well as domain scores for the Hospital VBP Program domains for which the hospital reports the minimum number of measures. We would then calculate a TPS for each eligible hospital and use the established methodology for converting the TPSs to value-based incentive payments for the given fiscal year.

3. Retention and Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Relationship Between the Hospital IQR and Hospital VBP Program Measure Sets

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41441), we finalized a revision to our regulations at 42 CFR 412.164(a) to clarify that once we have complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program, the statute does not require that the measure continue to remain in the Hospital IQR Program. We did not propose any changes to these policies in the proposed rule.

b. Measure Removal Factors for the Hospital VBP Program

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446), we finalized measure removal factors for the Hospital VBP Program, and we refer readers to that final rule for details. We did not propose any changes to these policies in the proposed rule.

c. Technical Measure Specification Updates To Include Covariate Adjustment for COVID–19 Beginning With the FY 2023 Program Year

In the FY 2022 IPPS/LTCH PPS final rule, we stated that we were updating the Hospital 30-Day, All-Cause, Risk -Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (MORT–30–AMI), Hospital 30-Day, All-Cause, Risk-

[275] CMS has also partnered with the CDC in a joint Call to Action on safety, which is focused on our core goal to keep patients safe. Fleisher et al. (2022). *New England Journal of Medicine.* Article available here: *https://www.nejm.org/doi/full/10.1056/NEJMp2118285?utm_source=STAT+Newsletters&utm_campaign=8933b7233e-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-8933b7233e-151759045.*

[276] McKinsey and Company. (2021). How COVID–19 is Reshaping Supply Chains. Available at: *https://www.mckinsey.com/business-functions/operations/our-insights/how-covid-19-is-reshaping-supply-chains.*

[277] Schneider, E. et al. (2022). *The Commonwealth Fund.* Responding to Omicron: Aggressively Increasing Booster Vaccinations Now Could Prevent Many Hospitalizations and Deaths. Available at: *https://www.commonwealthfund.org/blog/2022/responding-omicron.*

[278] KFF, Update on COVID–19 Vaccination of 5–11 Year Olds in the U.S., *https://www.kff.org/coronavirus-covid-19/issue-brief/update-on-covid-19-vaccination-of-5-11-year-olds-in-the-u-s/.*

[279] American Academy of Pediatrics. (2022). Summary of data publicly reported by the Centers for Disease Control and Prevention. Available at: *https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-vaccination-trends/.*

[280] Food and Drug Administration. (2022). Coronavirus (COVID–19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID–19 Vaccines for Children Down to 6 Months of Age. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children.*

[281] MacMillan, C. (2022) COVID–19 Vaccines for Kids Under 5: What Parents Need To Know. Available at: *https://www.yalemedicine.org/news/covid-19-vaccines-kids-under-5.*

[282] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID–19. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19.*

[283] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID–19 in Certain Adults. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain#:~:text=Today%2C%20the%20U.S.%20Food%20and,progression%20to%20severe%20COVID%2D19%2C.*

[284] The White House. (2022). Fact Sheet: The Biden Administration to Begin Distributing At-Home, Rapid COVID-19 Tests to Americans for Free. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/.*

[285] Miller, Z. 2021. *The Washington Post.* Biden to give away 400 million N95 masks starting next week Available at: *https://www.washingtonpost.com/politics/biden-to-give-away-400-million-n95-masks-starting-next-week/2022/01/19/5095c050-;7915-11ec-9dce-7313579de434_story.html.*

[286] The White House. (2022). FACT SHEET: Biden-Harris Administration Increases COVID-19 Testing in Schools to Keep Students Safe and Schools Open. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/12/fact-sheet-biden-harris-administration-increases-covid-19-testing-in-schools-to-keep-students-safe-and-schools-open/.*

Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG), Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30 COPD), Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization (MORT–30–HF), and Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP–HIP–KNEE) measures to exclude admissions with either a principal or secondary diagnosis of COVID–19 present on admission from the measure denominators beginning in FY 2023 (86 FR 45256 through 45258). We stated that we were making these updates pursuant to the technical updates policy we finalized in the FY 2015 IPPS/LTCH PPS final rule. Under this policy, we use a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital VBP Program (79 FR 50077 through 50079). As we stated in the FY 2022 IPPS/LTCH PPS final rule, we continue to believe that this subregulatory process is the most expeditious manner possible to ensure that quality measures remain fully up to date while preserving the public's ability to comment on updates that so fundamentally change a measure that it is no longer the same measure that we originally adopted (84 FR 42385).

As we continue to evaluate the effects of COVID–19 on the Hospital VBP Program measure set, we have observed that for some patients COVID–19 continues to have lasting effects, including fatigue, cough, palpitations, and others potentially related to organ damage, post viral syndrome, post-critical care syndrome or other reasons.[287] These clinical conditions could affect a patient's risk of mortality or complications following an index admission and, as a result, impact a hospital's performance on one or more of the four condition-specific mortality measures or the procedure-specific complication measure included in the Hospital VBP Program. In order to account for case mix among hospitals, the current risk adjustment approach for these measures include covariates for clinical comorbidities present on admission (POA) and in the 12 months prior to the index admission that are relevant and have relationships with the outcome, for example patient history of coronary artery bypass (CABG) surgery or history of mechanical ventilation. In accordance with the principles used during measure development and to adequately account for patient case mix, we are further modifying the technical measure specifications for the MORT–30–AMI, MORT–30–CABG, MORT–30–COPD, MORT–30–HF, and COMP–HIP–KNEE measures to include a covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission.

This inclusion of the covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission will be effective beginning with the FY 2023 program year for the MORT–30–AMI, MORT–30–CABG, MORT–30–COPD, MORT–30–HF, and COMP–HIP–KNEE measures. We will also include the covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission for the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN) measure. We note that, even though we previously finalized that we would suppress the MORT–30–PN measure for the FY 2023 program year, we would still publicly report the measure, and therefore, the inclusion of the covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission will still be effective beginning with the FY 2023 program year. We will delay sending MORT–30–PN confidential hospital feedback reports until October 2022 and delay public reporting until January 2023 to allow time for hospitals to become informed about this measure update and their hospital-level results. We will resume including hospital performance on the MORT–30–PN measure in the payment adjustment calculations, using the updated MORT–30–PN measure, beginning in FY 2024. We believe that making these updates to the MORT–30–PN measure for FY 2023 in hospitals' confidential feedback reports will allow hospitals the opportunity to preview these updates to the measure specifications in FY 2023 before they are used as part of payment adjustments for the FY 2024 program year.

For more information on the application of covariate adjustments, including the technical updates we are announcing in this final rule, please see the Measure Updates and Specifications Reports (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*).

Comment: Many commenters strongly supported the inclusion of patient history of COVID–19 in the 12 months prior to the index hospitalization as a covariate in the measures' risk adjustment models for the Hospital VBP Program mortality and complication measures starting in FY 2023. One of these commenters specifically agreed that a history of COVID–19 could affect a patient's risk for readmission and mortality. Another commenter added that the covariate for history of COVID–19 infection could allow tracking and better understanding of the effect of 'long COVID' on hospital performance and inform other potential pay for performance program changes, if indicated by the data. A few commenters stated that this update to risk-adjust measures for COVID–19 will be helpful to their healthcare organizations in particular, to prevent being unfairly penalized for caring for a high volume of COVID–19 patients.

Response: We thank the commenters for their support for the inclusion of a covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission for the mortality and complication measures included in the Hospital VBP Program.

Comment: Among commenters who supported the technical update to the measure specifications for MORT–30–AMI, MORT–30–CABG, MORT–30–COPD, MORT–30–HF, MORT–30 PN and COMP–HIP–KNEE measures to include a covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission, several commenters also strongly encouraged us to continue monitoring and evaluating the data to assess the full impact of COVID–19 on hospital operations, quality measures, and most importantly on patient health and outcomes, as the impact of 'long COVID' is still unknown. A few commenters urged us to continue to assess the measures' risk adjustment to determine if a 12-month period fully accounts for the impacts of 'long COVID–19' on these mortality measures. Another commenter noted that the most recent measure methodology reports show that history of COVID–19 is negatively correlated for outcomes measured for the five conditions in the domain for FY 2023. This commenter recommended that we only include the covariate adjustment for measures where it is a positive risk variable for the performance period in line with the proposal's intended recognition that history of COVID–19 could affect a patient's risk of mortality or complications.

[287] Raveendran, A.V., Jayadevan, R. and Sashidharan, S., *Long COVID: An overview.* Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8056514/.* Accessed on December 15, 2021.

Response: With regard to the rationale for adding the history of COVID–19 covariate to the model, analyses using data from 7/1/2020–2/28/2021 showed that for most of the mortality measures observed (unadjusted), 30-day mortality for patients without an index admission of COVID–19, but with a history of COVID–19 (defined as U07.1 or Z86.16 in the 12 months prior to the admission, or Z86.16 at the index admission), were higher than patients without a history of COVID–19. Based on the higher odds of death for these patients we decided to add the covariate across all of the condition- and procedure-specific mortality and complications measures in Hospital VBP Program. In the months since the publication of the FY 2023 IPPS/LTCH PPS proposed rule, we have analyzed newly available data and are providing updated information in this final rule. Specifically, results using more recent data spanning the entire 3-year reporting period (7/1/2018–6/30/2021) showed that for patients without an index admission of COVID–19, those with a history of COVID–19 (as defined in technical update) in the pneumonia and heart failure cohorts have much higher frequencies of some model risk variables compared with patients without a history of COVID–19, suggesting they are sicker.

We also found that the adjusted odds ratios for 30-day mortality for the history of COVID–19 variable (the odds ratios in the context of all of the variables in the model) are less than one (for all but the pneumonia mortality measure, where the odds of mortality are not statistically significant). In other words, in these patients without COVID–19, but with a history of COVID–19, the non-COVID–19 clinical comorbidities in the risk model are lessening or reversing the effect size of the history of COVID–19 variable. Nonetheless, we have decided to keep the history of COVID–19 covariate in the model along with the model's baseline risk factors in order to account for hospital case mix differences more effectively and for potential future impacts of long COVID–19 that the current measure does not currently account for.

Comment: Several commenters, while supportive of the technical update to incorporate a history of COVID–19 into the measures' risk adjustment models, raised concerns about the adequacy of the current codes and reliability of the existing data. A few of them specifically expressed concern that the covariate adjustment methodology which relies on the U07.1 or Z86.16 ICD–10–CM codes may not fully capture all patients who have had a history of COVID–19 and recommended further evaluation of additional codes or claims data. The commenters also suggested that the covariate adjustment methodology be reviewed by a special NQF Technical Expert Panel (TEP) to ensure that the adjustments are comprehensive enough to capture the long-term impacts of COVID–19.

Response: We appreciate commenters' concern about the adequacy of the current codes, and the implementation of the covariate in the model. Regarding coding adequacy, the history of COVID–19 variable is defined as U07.1 (COVID–19) or Z86.16 (personal history of COVID–1) in the 12 months prior to the admission, or Z86.16 at the index admission. Therefore, the history of COVID–19 variable does not rely solely on the COVID–19-specific ICD–10 code, U07.1, but also includes the ''personal history of COVID'' code (Z86.16) which hospitals can code even during the index encounter. With regard to additional variables related to a prior COVID–19 infection, we note that on October 1, 2021, the ICD–10 code U09.9 (Post COVID–19 condition, unspecified) was approved for implementation, which is another code that can be examined for future use in risk adjustment.

We thank commenters for their suggestion that a special NQF TEP review the covariate adjustment methodology to ensure that the adjustments are comprehensive enough to capture the long-term impacts of COVID–19. These changes to the measure, if permanent, will be reviewed by the NQF during the endorsement maintenance process. We will also continue to monitor the claims data and review the covariate adjustment methodology to evaluate the effect of history of COVID–19 on these quality measures and to determine appropriate policies in the future.

Comment: A few commenters supported the inclusion of patient history of COVID–19 in the 12 months prior to the index hospitalization as a covariate in the measures' risk adjustment models for the Hospital VBP Program mortality and complication measures starting in FY 2023 but urged us to conduct further analysis before implementing this change to ensure prior COVID–19 data are captured across hospitals in a complete, consistent, and equitable way. The commenters specifically urged us to examine and share publicly any data on variation in how prior COVID–19 is being captured in claims data. They also encouraged us to explore to what extent history of COVID–19 codes are capturing COVID–19 self-testing that patients may perform at home, and how frequently those codes are being used. The commenters also expressed concern that relying on the history of COVID–19 code could leave out a substantial portion of patients that may have had COVID–19, but did not get tested in an inpatient or ambulatory setting in the prior 12 months. Lastly, they recommended we continue to monitor the evolving evidence around post COVID–19 conditions to determine whether the 12-month timeframe should be lengthened or shortened. As the field continues to learn more about the ways in which 'long COVID' manifests itself, and the duration of its impacts, these commenters stated that our current approach may need to change.

Response: We appreciate commenters' recommendations regarding conducting further analysis to ensure prior COVID–19 data are captured across hospitals in a complete, consistent, and equitable way. The history of COVID–19 variable is defined as U07.1 (COVID–19) or Z86.16 (personal history of COVID–1) in the 12 months prior to the admission, or Z86.16 at the index admission. Therefore, the history of COVID–19 variable does not rely solely on the COVID–19-specific ICD–10 code, U07.1, but also includes the ''personal history of COVID'' code (Z86.16) which hospitals can code even during the index encounter. With regard to additional variables related to a prior COVID–19 infection, we note that on October 1, 2021, the CDC's National Center for Health Statistics implemented the ICD–10 code U09.9 (Post COVID–19 condition, unspecified), which is another code that can be examined for future use in risk adjustment. We will continue monitoring and evaluating additional data as they become available to understand the full impact of COVID–19 on healthcare organizations and patients to inform future program decisions.

Comment: A few commenters did not support risk adjusting for COVID–19 diagnosis within the condition- and procedure-specific mortality and complication Hospital VBP Program measures. They recommended adjusting the benchmarks instead for the achievement thresholds as well as reestablishing baselines inclusive of COVID–19 diagnosis. They also stated that the COVID–19 virus became a part of normal infection prevention care, and therefore its inclusion would inherently risk adjust the 2022 baseline for 2024 outcome data, effectively and appropriately leveling the playing field to the new normal.

Response: We interpret the commenter's statement to be referring to

adjustment of an index admission of COVID–19 and not a history of COVID–19, and therefore, we note that COVID–19 admissions have been excluded from the cohorts of these measures as outlined in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45256 through 45258). We thank commenters for their feedback. We will implement the inclusion of the covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission effective beginning with the FY 2023 program year for the MORT–30–AMI, MORT–30–CABG, MORT–30–COPD, MORT–30–HF, MORT–30–PN and COMP–HIP–KNEE measures.

d. Technical Updates to the Specifications for the MORT–30–PN Measure Beginning With the FY 2024 Program Year

In the FY 2022 IPPS/LTCH PPS final rule, pursuant to the measure suppression policy finalized in that rule and described in section V.I.1. of the preamble of this final rule, we finalized suppression of the MORT–30–PN measure (NQF #0468) for the FY 2023 program year (86 FR 45274 through 45276), and we refer readers to that final rule for additional information.

Since the publication of the FY 2022 IPPS/LTCH PPS final rule, we have continued to monitor the MORT–30–PN measure and have found that several factors, such as improved coding practices and decreased proportion of COVID–19 admissions for the MORT–30–PN cohort, have mitigated some of the impact of COVID–19 on this measure within certain data periods. Beginning in FY 2024 the MORT–30–PN measure will no longer be suppressed under the Hospital VBP Program. We are resuming the use of the MORT–30–PN measure for FY 2024 because of the following differences between the FY 2023 and FY 2024 performance periods: (1) the improved coding practices; (2) decreased proportion of COVID–19 admissions in the MORT–30–PN measure for this performance period; and (3) sufficient available data to make technical updates to the measure specifications in order to further account for how patients with a COVID–19 diagnosis might impact the quality of care assessed by this measure. Specifically, effective January 2021 the ICD10 code J12.82, Pneumonia due to coronavirus disease 2019, was added for use as a secondary diagnosis, along with a principal diagnosis of COVID–19 (U07.1), to identify patients with COVID–19 pneumonia. J12.82 is not included within the cohort of the MORT–30–PN measure, therefore mortality rates with pneumonia due to COVID–19 are not captured by this measure as of January 1, 2021. Whenever new codes are introduced, changes in coding practices are difficult to predict. At the time of the FY 2022 IPPS/LTCH PPS final rule, we did not have sufficient data to determine the effects of these coding changes on the proportion of COVID–19 patients and mortality rates with pneumonia due to COVID–19 in the MORT–30–PN measure. As additional months of data have become available since early 2021, we have now seen increased use of these codes. Secondly, as these coding changes have occurred and as the COVID–19 PHE has evolved, more recent data show the proportion of COVID–19 admissions in the MORT–30–PN measure have decreased compared to 2020 data. Finally, with the availability of additional data and the decrease in the proportion COVID–19 admissions in the MORT–30–PN measure, we are now able to make technical updates to the measure specifications in alignment with the technical updates we are making to four other mortality measures and one complication measure. Specifically, we are updating the technical specifications for the MORT–30–PN measure to exclude patients with either principal or secondary diagnoses of COVID–19 from the measure denominator beginning with the FY 2024 program year.

We are also updating the technical specifications for the MORT–30–PN measure to add a covariate that adjusts the measure outcome for a history of COVID–19 diagnosis in the 12 months prior to the admission (as discussed in section V.I.3.c. of the preamble of this final rule) and ensures alignment with the other four mortality and one complication measures. In our analysis, hospital-level MORT–30–PN measure scores calculated with the cohort and denominator exclusions and the addition of the covariate for a history of COVID–19 diagnosis in the 12 months prior (using data from July 1, 2018 through June 30, 2021, excluding admissions from December 2, 2019 through June 30, 2020 to apply the nationwide ECE granted due to the COVID–19 PHE (85 FR 54833 through 54835)), resulted in mean measure scores that were closer to the prior pre-COVID–19 period (July 1, 2017- through December 2, 2019) compared with the unchanged measure. We believe that excluding COVID–19 patients from the measure denominator, in addition to adjusting for a prior infection with COVID–19, will mitigate the impact of COVID–19 on this measure as much as is currently feasibly possible given the unpredictable nature of the pandemic, and ensure that this measure continues to reflect mortality rates as intended and meet the goals of the Hospital VBP Program beginning in FY 2024. We note that the MORT–30–PN measure uses three years of data. The performance period for the FY 2023 program year includes admissions from July 1, 2018 through June 30, 2021, exclusive of January 1, 2020 through June 30, 2020 data excluded due to the ECE waiver. Therefore, we continue to believe it is appropriate to suppress the currently implemented measure for use in payment calculations as finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45274 through 45276). The MORT–30–PN measure is also included in confidential feedback reports and public reporting on CMS' Care Compare website separate from the Hospital VBP Program use of the measure. Technical specifications of the Hospital VBP Program measures are provided on our website under the Measure Methodology Reports section (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*). Additional resources about the measure technical specifications and methodology for the Hospital VBP Program are on the QualityNet website (available at *https://qualitynet.cms.gov/inpatient/hvbp*).

Comment: Many commenters supported the technical updates to the MORT–30–PN measure to exclude admissions with either a principal or secondary diagnosis of COVID–19 present on admission from the measure denominator and to include a covariate for history of COVID–19 in the 12 months prior to admission. A commenter supported resuming the MORT–30–PN measure in the Hospital VBP Program in FY 2024. A few commenters also applauded our decision to publicly report the measure in January 2023 (2022 reporting period), even though the measure will be suppressed for FY 2023.

Response: We appreciate commenters' support. We note that the MORT–30–PN measure is suppressed in the Hospital VBP Program for FY 2023 and will resume in FY 2024. The October 2022 confidential reporting and January 2023 public reporting of the updated measure is to provide transparency and information to providers and patients on this important measure.

Comment: Many commenters supported the technical updates to the MORT–30–PN measure but urged us not to resume the use of this measure in the Hospital VBP Program for FY 2024 and to further evaluate the impact of

COVID–19 prior to resuming this measure. A commenter added that with these technical updates, the measure when considered in isolation appears to be structured appropriately to return to use in the Hospital VBP Program for FY 2024. However, we should consider the combined effects of the multiple program adjustments that have been made that would affect FY 2024 payment year determinations. The commenter recommended that we seriously consider the combined effects of data suppression and shortened performance period, along with any lingering impacts of COVID–19 that are uncovered by our monitoring in the interval prior to FY 2024 proposed rulemaking, in determining whether to again apply scoring and payment adjustments for FY 2024 payment determinations.

A few commenters recommended we conduct further analysis to ensure it has minimized the overlap between this measure and COVID–19-related pneumonia. The commenters also agree that these specification changes are directionally appropriate, and data included in the proposed rule shows a decline in the percentage of pneumonia patients with COVID–19 from January–July 2021. However, the commenters noted there were upticks in these percentages in August and September 2021 and suggested we run the same data for the entirety of 2021 to ensure these increases are anomalies rather than trends before re-introducing the MORT–30–PN measure into the Hospital VBP Program. This would enable agencies and the hospitals to determine whether additional education on the new codes is necessary, or if further measure specification tweaks may be required.

Response: We thank commenters for their feedback to conduct further evaluation of data and monitor the impact of COVID–19 before resuming the MORT–30–PN measure. Admissions for patients with a COVID–19 diagnosis will be removed from the measure, which means that the ''upticks'' in the percentage of COVID–19 admissions in the unmodified measure will not impact the cohort for the revised MORT–30–PN measure. As previously stated, our goal is to resume the use of measure data for scoring and payment adjustment purposes beginning with the FY 2024 program year. The October 2022 confidential reporting and January 2023 public reporting of the updated measure is to provide transparency and information to providers and patients on this important measure. Additionally, while we shortened the performance period for certain measures under the nationwide COVID–19 ECE, analyses show that the measures have a good reliability even when using a 30-month period versus a 36-month period.

e. Summary of Previously Adopted Measures for FY 2023 Through FY 2026 Program Years

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45281 through 45284) for summaries of previously adopted measures for the FY 2024 and FY 2025 program years, and to Table V.I.-03 in this section of the final rule showing summaries of previously adopted measures for the FY 2024, FY 2025, and FY 2026 program years. We proposed to suppress the HCAHPS and HAI measures for the FY 2023 program year. We did not propose to add new measures at this time. The Hospital VBP Program measure set for the FY 2023, FY 2024, FY 2025, and FY 2026 program years would contain the following measures:

TABLE V.I.-03: SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2023, FY 2024, FY 2025, FY 2026 PROGRAM YEARS

Measure Short Name	Domain/Measure Name	NQF #
Person and Community Engagement Domain		
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition measure)	0166 (0228)
Safety Domain		
CAUTI*	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI*	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI*	American College of Surgeons - Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)**	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) - Hospital	2158

* Per section V.I.l.b. of the preamble of this final rule, we are finalizing our proposal to suppress the HCAHPS and five HAI measures for the FY 2023 program year.

** In the FY 2022 IPPS/LTCH PPS final rule, we finalized our proposal to suppress the MORT-30-PN measure for the FY 2023 program year (86 FR 45274 through 45276).

4. Previously Adopted Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for a previously finalized schedule for all future baseline and performance periods for previously adopted measures. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256 through 38261), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41466 through 41469), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42393 through 42395), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58850 through 58854), and FY 2022 IPPS/LTCH PPS final rule (86 FR 45284 through 45290) for additional previously adopted baseline and performance periods for the FY 2024 and subsequent program years.

b. Updated Baseline Periods for Certain Measures Due to the COVID–19 PHE

(1) Background

We previously finalized baseline periods for the FY 2024, 2025, 2026, 2027, and 2028 program years for all the measures included in the Hospital VBP Program, and we refer readers to Tables V.I.–04 through V.I.–08 for those previously adopted baseline periods. However, subsequent to finalizing those baseline periods and, as described further in section V.I.1.b. of the preamble of this final rule, we proposed to suppress the HCAHPS and five HAI measures for the purposes of scoring and payment for FY 2023. Because these baseline periods are used to determine achievement thresholds and are used in awarding improvement scores to hospitals, we are concerned with using COVID–19 impacted data for the FY 2025 baseline periods for scoring and payment purposes.

Accordingly, to ensure that we have reliable data that are not unfairly affected by the COVID–19 PHE for baselining purposes, we proposed several updates to the baseline periods in this final rule for the FY 2025 program year.

We note that we proposed to update the baseline periods for certain measures under the Hospital VBP Program that have a 1-year baseline period. However, for measures that have baseline periods that span across multiple years, we believe the previously established baseline periods provide enough data from before and after CY 2021 to still calculate baseline

scores that would be reliable for scoring and payment purposes. Specifically, for the measures in the Clinical Outcomes domain (MORT–30–AMI, MORT–30–CABG, MORT–30–COPD, MORT–30–HF, MORT–30–PN, and COMP–HIP–KNEE), which have 36-month baseline periods, we did not propose any changes to the previously established baseline periods for FY 2025.

(2) Updated FY 2025 Baseline Period for the Person and Community Engagement Domain Measure (HCAHPS Survey)

In the FY 2017 IPPS/LTCH PPS final rule, we finalized that the baseline period for Person and Community Engagement Domain Measure (HCAHPS Survey) for the FY 2025 program year would be January 1, 2021 through December 31, 2021 (81 FR 56998). However, as more fully described in section V.I.1.b. of the preamble of this final rule, we have determined that the top-box scores for hospitals are significantly lower in Q1 and Q2 of CY 2021 than they were in Q1 and Q2 of CY 2019 (pre-pandemic), demonstrating the impact of COVID–19 on hospital performance for this measure. Therefore, in order to best mitigate the impact of using measure data affected by the COVID–19 PHE when determining achievement thresholds or awarding improvement points, we proposed to use a baseline period of January 1, 2019 through December 31, 2019 for the FY 2025 program year. This baseline period would be paired with a performance period of January 1, 2023 through December 31, 2023. We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2025 scoring. We are selecting this revised data period because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period, and it would capture a full year of data, including any seasonal effects.

Comment: Many commenters supported our proposal to establish new baseline periods for the HCAHPS measure, which has been impacted by the COVID–19 PHE. Commenters appreciated that our proposal would allow us to use a full-year of data unaffected by the COVID–19 PHE to compare to the CY 2023 performance period.

Response: We thank the commenters for their support of our proposal to update the baseline period for the HCAHPS measure for the FY 2025 program year.

Comment: A few commenters recommended that we continue to evaluate the impact of the pandemic as they set future policy and program adjustments related to baseline periods and performance standards.

Response: We appreciate the commenters' suggestions and note that we will continue to monitor the impact of the COVID–19 PHE on Hospital VBP Program data.

Comment: A commenter did not support our proposal for the HCAHPS 2019 baseline period, stating its belief that the proposed baseline is not reflective of current operations, safety protocols, and staffing. Instead, the commenter recommended we explore using alternative baseline periods, such as using all or part of CY 2021 or CY 2022 performance data as the baseline or using CY 2023 as both the baseline period and the performance period. The commenter also urged us to consider ways to modify the scoring policies for FY 2025 to incentivize improvement over achievement.

Response: We thank the commenter for the recommendation and note that we have chosen the 2019 baseline period to ensure that we have reliable data that are not unfairly affected by the COVID–19 PHE. We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2025 scoring and because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period. Because the pandemic has impacted hospitals and health systems in many different ways, and at different times, using an alternative baseline may unfairly penalize certain hospitals for circumstances out of their control. We do not believe it would be appropriate to use CY 2021 data as the baseline period because, as noted in section V.I.1.b.(2). of this final rule, we are finalizing the suppression the FY 2022 HCAHPS performance period, which uses CY 2021 data, because we believe that data has been impacted by the COVID–19 PHE. We note that we would not be able to use CY 2022 or CY 2023 data as the baseline period for the FY 2025 program year due to the operational time it takes to calculate performance standards and we would not be able to notify hospitals of the performance standards 60 days prior to the beginning of the performance period. Further, we believe that the current scoring methodology, which takes the higher of the improvement and achievement scores for a given measure, incentivizes hospitals to improve, while also incentivizing hospitals to continue striving for standards of care that would result in high quality of care.

Comment: A commenter did not support the proposed baseline period for the HCAHPS measure for the FY 2025 program year because it excludes COVID–19 data. The commenter recommended adjusting benchmarks and baselines to include COVID–19 diagnoses in the measure data, noting its belief that the COVID–19 virus has become part of normal infection prevention care and its inclusion would inherently risk adjust the 2022 baseline for 2024 outcome data.

Response: We appreciate the commenter's recommendation, but we believe it is not appropriate to use 2021 as the baseline because conditions related to the COVID–19 PHE in 2021 were not alike across the country, with some hospitals experiencing more staff shortages than others and geographic disparities in COVID–19 cases, with certain parts of the country experiencing more cases and greater strains on their health systems than others. Such conditions may have been out of their control and using a 2021 baseline would thus unfairly penalize the hospitals disproportionately impacted. Our proposed suppression, scoring, payment, and updated baseline policies have been developed to provide as much flexibility as we can for providers to focus on delivering care during the COVID–19 PHE. We intend to continue to consider the evolving COVID–19 PHE while also evaluating future policies so as to continue incentivizing hospitals to prioritize high quality of care for patients.

After consideration of the public comments we received, we are finalizing our proposal to update the baseline period for the HCAHPS measure for FY 2025 as proposed.

(3) Updated FY 2025 Baseline Period for the Safety Domain Measures

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized the performance period for all measures in the Safety domain to run on the calendar year two years prior to the applicable program year and a baseline period that runs on the calendar year four years prior to the applicable program year for the FY 2019 program year and subsequent program years. For FY 2025, the baseline period for the Safety domain measures would be January 1, 2021 through December 31, 2021. However, as more fully described in section V.I.1.b. of the preamble of this final rule, we have determined that the national measure rates for the HAI measures have significantly deviated in national performance in CY 2021,

indicating that the COVID–19 PHE has impacted performance on this measure. Therefore, in order to mitigate the impact of using measure data affected by the COVID–19 PHE when determining achievement thresholds or awarding improvement points, we proposed to use a baseline period of January 1, 2019 through December 31, 2019 for the FY 2025 program year. This baseline period would be paired with a performance period of January 1, 2023 through December 31, 2023. We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2025 scoring. We are selecting this revised data period because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period, and it would capture a full year of data, including any seasonal effects.

Comment: Many commenters supported our proposal to use updated baseline periods for the Safety Domain measures due to the COVID–19 pandemic, noting that it would allow us to use a full-year of data unaffected by the COVID–19 PHE to compare to the CY 2023 performance period. A few commenters recommended that we consider the impact of COVID–19 in future policies.

Response: We thank the commenters for their support of the updated baseline periods for the Safety Domain measures. We will continue to monitor the impact of the PHE on program data and will take commenters' concerns and recommendations under consideration for future rulemaking.

Comment: A commenter did not support our proposal to use CY 2019 as the updated baseline period for each of the Safety Domain measures because the commenter believes the updated baseline periods are not reflective of current operations and recommended we explore alternative baseline periods. A commenter did not support our proposal because the baseline periods exclude COVID–19 data and the commenter believes that the pandemic has become a part of normal infection prevention care and should thus be included in the 2022 baseline period for 2024 outcome data.

Response: We appreciate the commenter's recommendation, but we believe it is not appropriate to use a more recent baseline period inclusive of COVID–19 data because conditions related to the COVID–19 PHE are not alike across the country, with some hospitals experiencing more staff shortages than others and geographic disparities in COVID–19 cases. Such conditions may have been out of their control and using a more recent baseline inclusive of COVID–19 data would thus unfairly penalize the hospitals disproportionately impacted. Our proposed suppression, scoring, payment, and updated baseline policies have been developed to provide as much flexibility as we can for providers to focus on delivering care during the COVID–19 PHE. We intend to continue to consider the evolving COVID–19 PHE while also evaluating future policies so as to continue incentivizing and prioritizing high quality of care for patients.

After consideration of the public comments we received, we are finalizing our proposal to use updated baseline periods for the 5 HAI measures for FY 2025 as proposed.

c. Summary of Previously Adopted and Newly Baseline and Performance Periods for the FY 2024 Through FY 2028 Program Years Tables V.I.–04 Through 08 Summarize the Baseline and Performance Periods That We Have Previously Adopted and Those That We Are Finalizing

TABLE V.I.-04: PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2024 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2019 – December 31 2019*	January 1, 2022 – December 31 2022
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2014 – June 30, 2017	July 1, 2019 – June 30, 2022**
COMP-HIP-KNEE	April 1, 2014 – March 31, 2017	April 1, 2019 – March 31, 2022**
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2019 – December 31 2019*	January 1, 2022 – December 31 2022
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2019 – December 31 2019*	January 1, 2022 – December 31 2022

*In the FY 2022 IPPS/LTCH PPS final rule, we finalized that these baseline periods would be January 1, 2019 through December 31, 2019 (86 FR 45284 through 45285).

**In accordance with the ECE granted in response to the COVID-19 PHE and the policies finalized in the September 2, 2020 interim final rule with comment titled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency," (85 FR 54820), we will not use Q1 and Q2 2020 data that was voluntarily submitted for scoring purposes under the Hospital VBP Program.

TABLE V.I.-05: PREVIOUSLY ADOPTED AND BASELINE AND PERFORMANCE PERIODS FOR THE FY 2025 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2019 – December 31 2019*	January 1, 2023 – December 31 2023
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2015 – June 30, 2018	July 1, 2020 – June 30, 2023
COMP-HIP-KNEE	April 1, 2015 – March 31, 2018	April 1, 2020 – March 31, 2023**
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2019 – December 31 2019*	January 1, 2023 – December 31 2023
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2021 – December 31 2021	January 1, 2023 – December 31 2023

*As described more fully in section V.I.4.b. of the preamble of this final rule, we are finalizing our proposals to update the baseline periods for the measures included in the Person and Community Engagement and Safety domains for FY 2025.
**In accordance with the ECE granted in response to the COVID-19 PHE and the policies finalized in the September 2, 2020 interim final rule with comment titled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency," (85 FR 54820), we will not use Q1 and Q2 2020 data that was voluntarily submitted for scoring purposes under the Hospital VBP Program.

TABLE V.I.-06: PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2026 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2022 – December 31 2022	January 1, 2024 – December 31 2024
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2016 – June 30, 2019	July 1, 2021 – June 30, 2024
COMP-HIP-KNEE	April 1, 2016 – March 31, 2019	April 1, 2021 – March 31, 2024
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2022 – December 31 2022	January 1, 2024 – December 31 2024
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2022 – December 31 2022	January 1, 2024 – December 31 2024

TABLE V.I.-07: PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2027 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2023 – December 31 2023	January 1, 2025 – December 31 2025
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2017 – June 30, 2020**	July 1, 2022 – June 30, 2025
COMP-HIP-KNEE	April 1, 2017 – March 31, 2020**	April 1, 2022 – March 31, 2025
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2023 – December 31 2023	January 1, 2025 – December 31 2025
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2023 – December 31 2023	January 1, 2025 – December 31 2025

**These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE V.I.-08: PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2028 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2024 – December 31 2024	January 1, 2026 – December 31 2026
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2018 – June 30, 2021**	July 1, 2023 – June 30, 2026
COMP-HIP-KNEE	April 1, 2018 – March 31, 2021**	April 1, 2023 – March 31, 2026
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2024 – December 31 2024	January 1, 2026 – December 31 2026
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2024 – December 31 2024	January 1, 2026 – December 31 2026

**These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

5. Performance Standards for the Hospital VBP Program

a. Background

We refer readers to sections 1886(o)(3)(A) through 1886(o)(3)(D) of the Act for the statutory provisions governing performance standards under the Hospital VBP Program. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program. We refer readers to the FY 2013 IPPS/LTCH PPS final rule, FY 2014 IPPS/LTCH PPS final rule, and FY 2015 IPPS/LTCH PPS final rule (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50077 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45290 through 45292) for previously established performance standards for the FY 2024 program year. We note that the measure suppression proposals for the FY 2023 program year, discussed more fully in section V.I.1.b. of this final rule, will not affect the performance standards for the FY 2023 program year. However, as discussed in section V.I.1.c. of this final rule, we proposed to not generate achievement or improvement points for any suppressed measures for FY 2023.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for further discussion on performance standards for which the measures are calculated with lower values representing better performance (85 FR 58855).

b. Previously Established and Estimated Performance Standards for the FY 2025 Program Year

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42398 through 42399), we established performance standards for the FY 2025 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and for the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB

measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. As discussed in section V.I.4.b. of this final rule, we proposed to update the FY 2025 program year baseline periods for the measures included in the Safety domain and Person and Community Engagement domain, and we have finalized these baseline periods as proposed. In the proposed rule, we stated that if these proposals are finalized, we would use data from January 1, 2019 through December 31, 2019 to calculate performance standards for the FY 2025 program year for these measures.

In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) and codified at 42 CFR 412.160, we are estimating additional performance standards for the FY 2024 program year. We note that the numerical values for the performance standards for the Safety domain and Person and Community Engagement domain for the FY 2025 program year in Tables V.I.–09 and V.I.–10 were calculated using data from January 1, 2019 through December 31, 2019. Therefore, in the FY 2023 IPPS/LTCH PPS proposed rule, we stated that if our proposed updates to the baseline periods for these measures are finalized, we will not update the numerical values in the FY 2023 IPPS/LTCH PPS final rule. As stated in section V.I.4.c. of this final rule, we are finalizing the proposed updates to the baseline period for these measures as proposed.

The previously established and estimated performance standards for the measures in the FY 2025 program year have been updated and are set out in Tables V.I.–09 and V.I.–10.

TABLE V.I.-09: PREVIOUSLY ESTABLISHED AND NEWLY ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2025 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Safety Domain♦		
CAUTI*	0.735	0
CLABSI*	0.918	0.013
CDI*	0.427	0
MRSA Bacteremia*	0.969	0.026
Colon and Abdominal Hysterectomy SSI*	0.716 0.824	0 0
Clinical Outcomes Domain		
MORT-30-AMI#	0.872624	0.889994
MORT-30-HF#	0.883990	0.910344
MORT-30-PN (updated cohort)#	0.841475	0.874425
MORT-30-COPD#	0.915127	0.932236
MORT-30-CABG#	0.970100	0.979775
COMP-HIP-KNEE*#	0.025332	0.017946
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

♦ As discussed in section V.I.4.b. of this final rule, we proposed to update the FY 2025 baseline periods for measures included in the Person and Community Engagement and Safety domains to use CY 2019 data. Therefore, the performance standards displayed in this table for the Safety domain measures were calculated using CY 2019 data.

* Lower values represent better performance.

Previously established performance standards.

The HCAHPS Base Score is calculated using the eight dimensions of the HCAHPS measure. For each of the eight dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is then summed across the eight dimensions to create the HCAHPS Base Score (0–80 points). Each of the eight dimensions is of equal weight; therefore, the HCAHPS Base Score ranges from 0 to 80 points. HCAHPS Consistency Points are then calculated, which range from 0 to 20 points. The Consistency Points take into consideration the scores of all eight Person and Community Engagement dimensions. The final element of the scoring formula is the summation of the HCAHPS Base Score and the HCAHPS Consistency Points, which results in the Person and Community Engagement domain score that ranges from 0 to 100 points. As discussed in section V.I.4.b.(2). of this final rule, we proposed to update the FY 2025 program year baseline period for the measure included in the Person and Community Engagement domain. We are finalizing that proposal and, according to our established methodology for calculating performance standards, we will use data from January 1, 2019 through December 31, 2019 to calculate performance standards for the FY 2025 program year for this measure.

TABLE V.I.-10: ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2025 PROGRAMYEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN±

HCAHPS Survey Dimension	Floor (minimum)	Achievement Threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	53.50	79.42	87.71
Communication with Doctors	62.41	79.83	87.97
Responsiveness of Hospital Staff	40.40	65.52	81.22
Communication about Medicines	39.82	63.11	74.05
Hospital Cleanliness & Quietness	45.94	65.63	79.64
Discharge Information	66.92	87.23	92.21
Care Transition	25.64	51.84	63.57
Overall Rating of Hospital	36.31	71.66	85.39

± As discussed in section V.I.4.b.(2). of this final rule, we are finalizing our proposal to update the FY 2025 baseline periods for measures included in the Person and Community Engagement and Safety domains to use CY 2019 data. Therefore, the performance standards displayed in this table for the Person and Community Engagement domain measures were calculated using CY 2019 data.

c. Previously Established Performance Standards for Certain Measures for the FY 2026 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58858 through 58859), we established performance standards for the FY 2026 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for these measures are set out in the Table V.I.–11.

TABLE V.I.-11: PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2026 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain		
MORT-30-AMI	0.874426	0.890687
MORT-30-HF	0.885949	0.912874
MORT-30-PN (updated cohort)	0.843369	0.877097
MORT-30-COPD	0.914691	0.932157
MORT-30-CABG	0.970568	0.980473
COMP-HIP-KNEE*	0.024019	0.016873
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

d. Previously Established Performance Standards for Certain Measures for the FY 2027 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45294 through 45295), we established performance standards for the FY 2027 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for these measures are set out in Table V.I.–12.

TABLE V.I.-12: PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2027 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain**		
MORT-30-AMI	0.877824	0.893133
MORT-30-HF	0.887571	0.913388
MORT-30-PN (updated cohort)	0.844826	0.877204
MORT-30-COPD	0.917395	0.932640
MORT-30-CABG	0.971149	0.980752
COMP-HIP-KNEE*	0.023322	0.017018
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 5297 through 45299), we did not include data from Q1 and Q2 of CY 2020 in the calculation of these performance standards.

e. Newly Established Performance Standards for Certain Measures for the FY 2028 Program Year

As discussed previously, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB) for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513), which is codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2028 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in Table V.I.–13.

TABLE V.I.-13 NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2027 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain**		
MORT-30-AMI	0.877260	0.893229
MORT-30-HF	0.885427	0.910649
MORT-30-PN (updated cohort)	0.831776	0.866166
MORT-30-COPD	0.913752	0.929652
MORT-30-CABG	0.971052	0.980570
COMP-HIP-KNEE*	0.029758	0.022002
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** We note that these performance standards are calculated using some data from CY 2020 and CY 2021, which are included the COVID-19 PHE. However, these performance standards have been calculated using the updated technical specifications described in sections V.I.3.c. and V.I.3.d. of this final rule, which excludes patients diagnosed with COVID-19 and risk-adjusts for history of COVID-19 for these measures.

6. Data Requirements

a. Domain Weighting for Hospitals That Receive a Score on All Domains

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266), we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the Hospital VBP Program for the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. We did not propose any changes to these domain weights.

b. Domain Weighting for Hospitals Receiving Scores on Fewer Than Four Domains

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085), we adopted a policy that hospitals must

receive domain scores on at least three of four quality domains in order to receive a TPS, for the FY 2017 program year and subsequent years. Hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted (79 FR 50084 through 50085). We did not propose any changes to these domain weights.

c. Minimum Numbers of Measures for Hospital VBP Program Domains

We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266) for our previously finalized requirements for the minimum numbers of measures for hospitals to receive domain scores. We did not propose any changes to these policies.

d. Minimum Numbers of Cases for Hospital VBP Program Measures

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53610); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267). We did not propose any changes to these policies.

(2) Summary of Previously Adopted Minimum Numbers of Cases

The previously adopted minimum numbers of cases for these measures are set forth in Table V.I.–14.

TABLE V.I.-14: PREVIOUSLY ADOPTED MINIMUM CASE NUMBER REQUIREMENTS FOR HOSPITAL VBP PROGRAM

Measure Short Name	Minimum Number of Cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Outcomes Domain	
MORT-30-AMI	Hospitals must report a minimum number of 25 cases.
MORT-30-HF	Hospitals must report a minimum number of 25 cases.
MORT-30-PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT-30-COPD	Hospitals must report a minimum number of 25 cases.
MORT-30-CABG	Hospitals must report a minimum number of 25 cases.
COMP-HIP-KNEE	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

e. Summary of Previously Adopted Administrative Policies for NHSN Healthcare-Associated Infection (HAI) Measure Data

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42400 through 42402), we finalized our proposal to use the same data to calculate the CDC NHSN HAI measures for the Hospital VBP Program that the HAC Reduction Program uses for purposes of calculating the measures under that program, beginning on January 1, 2020 for CY 2020 data collection, which would apply to the Hospital VBP Program starting with data for the FY 2022 program year performance period. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42402), we also finalized our proposal for the Hospital VBP Program to use the same processes adopted by the HAC Reduction Program for hospitals to review and correct data for the CDC NHSN HAI measures and to rely on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program. We did not propose any changes to these policies.

7. Extraordinary Circumstance Exception (ECE) Policy for the Hospital VBP Program

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45298 through 45299) for additional details related to the Hospital VBP Program ECE policy. We did not propose any changes to the Hospital VBP Program ECE policy.

8. References to Requests for Information

a. NHSN Digital Quality Measures

We also refer readers to section IX.E.9.a. of this final rule, where we received comments in response to our request for information on the potential future adoption of the National Healthcare Safety Network (NHSN) Healthcare-Associated *Clostridioides difficile* Infection Outcome Measure and the National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure into the Hospital IQR Program. In addition, we requested information on the potential future inclusion of these digital CDC NHSN measures in the Hospital VBP Program. This request for information supports our goal of moving fully to digital quality measurement in CMS quality reporting and value-based purchasing programs, including the Hospital VBP Program.

b. Reference to the Request for Information: Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

We refer readers to section IX.B. of this final rule where we received input on overarching principles in measuring healthcare quality disparities in hospital quality and value-based purchasing programs.

J. Hospital-Acquired Condition (HAC) Reduction Program: Updates and Changes (42 CFR 412.170)

1. Regulatory Background

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program and to the same final rule (78 FR 50708 through 50709) for a detailed discussion of the statutory basis for the Program. For additional descriptions of our previously finalized policies for the HAC Reduction Program, we also refer readers to the following final rules:

- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57011 through 57026);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38269 through 38278);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42402 through 42411);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58860 through 58865); and
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45300 through 45310).

We have also codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

2. Flexibility for Changes That Affect Quality Measures During a Performance or Measurement Period in the HAC Reduction Program

a. Measure Suppression Policy for the Duration of the COVID–19 PHE

In the FY 2022 IPPS/LTCH PPS final rule, we adopted a policy for the duration of the COVID–19 PHE enabling us to suppress a number of measures from the Total HAC Score calculations for the HAC Reduction Program if we determine that circumstances caused by the COVID–19 PHE have affected these measures and the resulting Total HAC Scores significantly (86 FR 45301 through 45304). We refer readers to the FY 2022 IPPS/LTCH PPS final rule for further details on our measure suppression policy (86 FR 45301 through 45304).

In the FY 2022 IPPS/LTCH PPS final rule, we also adopted Measure Suppression Factors to guide our determination of whether to propose to suppress HAC Reduction Program measures for one or more program years that overlap with the PHE for COVID–19 (86 FR 45302). We adopted these Measure Suppression Factors for use in the HAC Reduction Program, and, for consistency, in the following other value-based purchasing programs: Hospital Value-Based Purchasing Program, Hospital Readmissions Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and End-Stage Renal Disease Quality Incentive Program. We continue to believe that these Measure Suppression Factors will help us evaluate the HAC Reduction Program's measures, and that their adoption in the other value-based purchasing programs will help ensure consistency in our measure evaluations across programs. The previously adopted Measure Suppression Factors are as follows:

- Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID–19 PHE.
- Rapid or unprecedented changes in—

++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

++ The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

- Significant national shortages or rapid or unprecedented changes in—

++ Healthcare personnel;

++ Medical supplies, equipment, or diagnostic tools or materials; or

++ Patient case volumes or facility-level case mix.

We stated that we view this measure suppression policy as necessary to ensure that the HAC Reduction Program does not reward or penalize facilities based on factors that the Program's measures were not designed to accommodate (86 FR 45302).

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28446 through 28449), we proposed changes to this measure suppression policy, which we discuss in section V.J.2.b.(2).

b. Proposals To Apply the Measure Suppression Policy to FY 2023 and FY 2024 HAC Reduction Program Years

(1) Background

Through memoranda released in March 2020 [288] and an interim final rule with comment (IFC) published in September 2020 (85 FR 54830 through 54832), in response to the COVID–19 PHE, we excluded, by application of our Extraordinary Circumstances Exception (ECE) policy, all data submitted regarding care provided during the first and second quarters of CY 2020 from our performance calculations for FY 2022 and FY 2023. We excluded such data because of our concerns about the national comparability of these data due to the geographic differences of COVID–19 incidence rates and hospitalizations, along with different impacts resulting from different State and local laws and policy changes implemented in response to COVID–19.

Additionally, in the FY 2022 IPPS/LTCH PPS final rule, we finalized our policy suppressing the third and fourth quarters of CY 2020 [289] CDC NHSN HAI and the CMS Patient Safety and Adverse Events Composite measure (CMS PSI 90) data from our performance calculations for FY 2022, FY 2023, and FY 2024 under the proposed Measure Suppression Factor 1, ''significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years''; and the Measure Suppression Factor 4 subfactor, ''significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix'' (86 FR 45304 through 45307). We explained that although Q3 and Q4 2020 data would be suppressed from the Total HAC Score calculation, hospitals would still be required to submit such

[288] Centers for Medicare and Medicaid Services. (2020). Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 Available at: *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*.

[289] In the FY 2022 IPPS/LTCH PPS final rule, we finalized the suppression of the third and fourth quarters of CY 2020, which is July 1, 2020 through September 30, 2020 (Q3 2020) and October 1, 2020 through December 31, 2020 (Q4 2020).

data and such data would be used for public reporting purposes.

These policies resulted in the following applicable periods for calculating Total HAC Scores for FY 2022, FY 2023, and FY 2024 HAC Reduction Programs:

Applicable Periods for FY 2022, FY 2023, and FY 2024 for the HAC Reduction Program		
Fiscal Year	**Measure Set**	**Current Applicable Periods that Resulted from ECE and Measure Suppression Policies**
FY 2022	CDC NHSN HAI	January 1, 2019 through December 31, 2019
	CMS PSI 90	July 1, 2018 through December 31, 2019
FY 2023	CDC NHSN HAI	January 1, 2021 through December 31, 2021
	CMS PSI 90	July 1, 2019 through December 31, 2019 and January 1, 2021 through June 30, 2021
FY 2024	CDC NHSN HAI	January 1, 2021 through December 31, 2022
	CMS PSI 90	January 1, 2021 through June 30, 2022

In sections V.J.2.b.(2). and (3), of this final rule, we are finalizing the proposal to further modify some of these applicable periods.

(2) Updates to the FY 2023 HAC Reduction Program

In the FY 2023 IPPS/LTCH proposed rule, we discussed two updates for the FY 2023 HAC Reduction Program's measure suppression policy: (1) We proposed to suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score, thereby not penalizing any hospital under the FY 2023 HAC Reduction Program; and (2) For the CMS PSI 90 measure, we proposed to not calculate or report measure results for the FY 2023 HAC Reduction Program.

COVID–19 has had significant negative health effects—on individuals, communities, and the nation as a whole. Consequences for individuals who have COVID–19 include morbidity, hospitalization, mortality, and post-COVID conditions (also known as long COVID). As of mid-December 2021, over 50 million COVID–19 cases, three million new COVID–19 related hospitalizations, and over 800,000 COVID–19 deaths have been reported in the U.S.[290] [291] One analysis projected that COVID–19 would reduce life expectancy in 2020 by 1.13 years overall, with the estimated impact disproportionately affecting members of historically underserved and under-resourced communities. According to this analysis, the estimated life expectancy reduction for Black and Latino populations is three to four times the estimate when comparing to the white population.[292] Indeed, COVID–19 has overtaken the 1918 influenza pandemic as the deadliest disease event in American history.[293] Impacts of the pandemic have continued to accelerate in 2021. The Delta variant of COVID–19 (B.1.617.2), which was first identified in India, surfaced in the United States in early-to-mid 2021. It was found that the Delta variant is 60 percent more transmissible compared to the previously dominant Alpha variant.[294] Further, in November 2021, the number of COVID–19 deaths for 2021 surpassed the total deaths for 2020. According to CDC data, the total number of deaths involving COVID–19 reached 385,453 in 2020 and 451,475 in 2021.[295] We continue to monitor and evaluate the measures in the HAC Reduction Program for impacts due to COVID–19 and the emergence of COVID–19 variants, such as Delta and Omicron variants, and elaborate further later in the section.

As described in section V.J.2.b.(1). of this final rule, we previously excluded or suppressed all quarters of CY 2020 data from the calculation of the Total HAC Score, in part, because of concerns about the national comparability of these data and significant deviation in national performance on the measure compared to historical performance. We acknowledge that facilities were still adapting to the demands of the PHE and that subsequently national performance deviated from previous performance during CY 2021. Therefore, we proposed to suppress all HAC Reduction Program measures (CMS PSI 90, CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) from the calculation of the Total HAC Score for the FY 2023 HAC Reduction Program under Measure Suppression Factor 1 significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; and Measure Suppression Factor 4, significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix.

We are concerned that the COVID–19 PHE resulted in changes in HAC Reduction Program measure performance such that we would not be able to score hospitals fairly. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45304 through 45305) for previous analysis on the HAC Reduction Program measures that showed that measure rates for the CLABSI, CAUTI, and MRSA measures increased during the CY 2020 pandemic year as compared to the pre-COVID CY 2019 year immediately preceding the COVID–19 PHE.

In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to suppress three of the five CDC NSHN HAI measures (CLABSI, CAUTI, and MRSA) under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to

[290] Centers for Disease Control and Prevention. (2021). COVID Data Tracker, *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[291] As of mid-June 2022, over 86 million COVID–19 cases, 15,000 new COVID–19 related hospitalizations, and over a million COVID–19 deaths have been reported in the U.S.

[292] Andrasfay, T., & Goldman, N. (2021). Reductions in 2020 US life expectancy due to COVID–19 and the disproportionate impact on the Black and Latino populations. Proceedings of the National Academy of Sciences of the United States of America, 118(5), e2014746118. *https://www.pnas.org/content/118/5/e2014746118.*

[293] STAT News. (2021). Covid-19 overtakes 1918 Spanish flu as deadliest disease in American history, *https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history/.*

[294] Allen H., Vusirikala A., Flannagan J., et al. Increased Household Transmission of COVID–19 cases associated with SARS–CoV–2 Variant of Concern B.1.617.2: a national case-control study. Public Health England. 2021.

[295] Centers for Disease Control. (2022). COVID–19 Death Data and Resources. Available at: *https://www.cdc.gov/nchs/nvss/covid-19.htm.*

historical performance during the immediately preceding program years. To determine whether the CLABSI, CAUTI, and MRSA measure rates would continue to show increases for CY 2021, the CDC analyzed changes in standardized infection ratios (SIRs) for Q1 and Q2 of CY 2021 as compared to the SIRs in Q1 and Q2 of CY 2019. This analysis found that the CLASBI, CAUTI, and MSRA measures had statistically significant measure rate increases during Q1 and Q2 of CY 2021 as compared to pre-pandemic levels in Q1 and Q2 of CY 2019. For Q1 2021, the national SIR increased by approximately 45 percent for the CLABSI measure, approximately 12 percent for the CAUTI measure, and approximately 39 percent for the MRSA measure as compared to Q1 2019. For Q2 2021, the national SIR increased by approximately 15 percent for the CLABSI measure and approximately 8 percent for the MRSA measure. The SIRs for the CAUTI measure showed no statistically significant difference for Q2 2021 as compared to Q2 2019.

For the CDI measure, the national SIR decreased by approximately 16 percent for Q1 2021 as compared to Q1 2019 and by approximately 14 percent for Q2 2021 as compared to Q2 2019. The SSI measure showed no significant increase or decrease in SIRs during Q1 2021 and Q2 2021 as compared to Q1 2019 and Q2 2019, however there has been an appreciable decrease in procedure volume for the measure. We proposed to suppress the SSI and CDI measures under Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in patient case volumes and Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials, respectively. Specifically, for the SSI measure, we proposed to suppress the measure for FY 2023 under Measure Suppression Factor 4, rapid or unprecedented changes in patient case volumes. We note that the SSI measure has had a low procedure volume for many hospitals during the PHE, which impacts our ability to produce SIRs for that measure. For CY 2019, 2,087 hospitals (61 percent) did not have sufficient procedure-level data needed to calculate an SSI SIR for abdominal hysterectomy, and 1,262 hospitals (37 percent) did not have sufficient data to calculate an SIR for colon surgery. However, nationally, procedure volumes declined even further during the COVID–19 PHE in 2020, compared to 2019, with decreases of up to 23 percent for colon procedures and 39 percent for abdominal hysterectomy procedures.[296] As of July 2021, abdominal hysterectomy procedures were still 6 percent below predicted levels.[297] These changes in patient volumes for the SSI measure limit our ability to calculate SSI SIRs for hospitals that don't have sufficient data in FY 2023, which may impact the accuracy and reliability of overall national comparison on performance for this measure.

For the CDI measure, we proposed to suppress the measure under Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, related protocols, or equipment or diagnostic tools or materials. Pandemic-related improvements to typical CDI prevention practices such as hand hygiene, PPE practices, and environmental cleaning could have contributed to the declines seen in the CDI SIR in 2021 compared to 2019.[298] In addition, a decline in outpatient antibiotic prescribing was observed starting in 2020 as healthcare utilization decreased during the COVID–19 pandemic.[299] This, combined with the continued use of inpatient antibiotic stewardship programs in hospitals, may also have contributed to the decline in the national CDI SIRs, as reducing patient antibiotic exposure is a recommended strategy for CDI prevention. More information about CDI prevention strategies can be found at *https://www.cdc.gov/cdiff/clinicians/cdi-prevention-strategies.html*.

PERCENT CHANGES IN SIRS COMPARED TO RESPECTIVE 2019 QUARTERS

	2020 Q1	2020 Q2	2020 Q3	2020 Q4	2021 Q1	2021 Q2	2021 Q3*
CLABSI	-11.8	27.9	46.4	47.0	45.3	14.6	48.6
CAUTI	-21.3	No change	12.7	18.8	11.5	No change	12.7
SSI: Colon surgery	-9.1	No change	-6.9	-8.3	No change	No change	No change
SSI: Abdominal hysterectomy	-16.0	No change	No change	-13.1	No change	No change	No change
MRSA bacteremia	-7.2	12.2	22.5	33.8	39.2	8.3	40.7
CDI	-17.5	-10.3	-8.8	-5.5	-15.6	-14.1	-15.8

* The Q3 2021 HAI measure data has been finalized since the publication of the FY 2023 IPPS/LTCH proposed rule. In this final rule, we have updated the table to reflect the final figures.

Additionally, because we cannot identify all potential elements that could be impacting the overall HAI experience at hospitals during an unprecedented PHE as well as potential geographic disparities in the impact of the PHE that could cause uneven impact on facilities based on their location, like shortages of healthcare personnel, we believe all five CDC NHSN HAI measures should be suppressed. Therefore, we believe it is appropriate to suppress all five HAI measures from the HAC Reduction Program for the FY 2023 program year, to ensure an accurate and reliable national comparison of performance on hospital safety.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45304 through 45305), we observed that the skewed measure

[296] Weiner-Lastinger, L., et al,. The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology (2022), 43, 12–25. doi:10.1017/ice.2021.362.

[297] Butler, S., et al. (2021). Epic Research. Elective Surgeries Approach Pre-Pandemic Volumes. Available at: *https://epicresearch.org/articles/elective-surgeries-approach-pre-pandemic-volumes*.

[298] Weiner-Lastinger L.M., et al. (2021). The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology, *https://doi.org/10.1017/ice.2021.362*.

[299] The intersection of antibiotic resistance (AR), antibiotic use (AU), and COVID–19. (2021). Department of Health and Human Services website. *https://www.hhs.gov/sites/default/files/antibiotic-resistance-antibiotic-use-covid-19-paccarb.pdf*. Published February 10, 2021. Accessed June 28, 2021.

performance may be due to circumstances unique to the effects of the pandemic such as staffing shortages and turnover, patients who are more susceptible to infections due to increased hospitalization stays, and longer indwelling catheters and central lines. We believe that the continued skewed measure performance is impacted by similar circumstances unique to the effects of the COVID–19 PHE. We further believe that our proposal to suppress the HAI measure data from CY 2021 was appropriate because the impact of the COVID–19 PHE on the measures cannot be addressed through risk-adjustment. Under current data collection requirements for the CDC NHSN HAI measures the data are collected at each hospital's ward level, meaning that the hospital submits infection data for a given ward rather than at the individual patient level. Accordingly, we are not able to identify the number of patients with HAIs who also had COVID–19, and therefore cannot risk-adjust for or otherwise account for COVID–19 diagnoses. Modifying CDC's risk adjustment methodology is a multi-year process that requires substantial time to review, analyze, and implement updated methodology for the calculation of the SIR. In order to address the impact of the ongoing COVID–19 PHE on HAI incidence, as reported to CDC NHSN, we believe suppression of the CY 2021 measure data is the best path forward for participating hospitals. Therefore, we proposed to suppress all five HAI measures in the HAC Reduction Program for the FY 2023 program year.

In accordance with the previously adopted measure suppression policy (86 FR 45301 through 45304), we proposed to suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures for the HAC Reduction Program FY 2023 program year. We will continue to provide the measure results for the CDC NHSN HAI measures to hospitals via their hospital-specific reports (HSRs). We will also continue providing information regarding hospital performance to hospitals and other interested persons via the Care Compare tool hosted by Health and Human Services, currently available at *https://www.medicare.gov/care-compare*, and the Provider Data Catalog. As previously noted, under this policy, we would continue to use claims data for the CMS PSI 90 measure and participating hospitals would continue to report CDC NHSN HAI measure data to the CDC, so that we can monitor the effect of the circumstances on quality measurement and determine appropriate policies in the future.

Similarly, our analysis of the CMS PSI 90 measure suggested that comparability of performance on the measure has also been impacted by the PHE. Additionally, after the nationwide ECE (85 FR 54827 through 54828) and the FY 2022 IPPS/LTCH PPS final rule measure suppression policies (86 FR 45304 through 45307) the CMS PSI 90 measure reference period for the FY 2023 program year does not include data affected by the COVID–19 PHE. Conversely, the applicable period for the CMS PSI 90 measure does include data affected by COVID–19 PHE. Due to the fact that the reference period for this measure does not include data affected by the COVID–19 PHE and the applicable period does include such data, this would result in risk adjustment parameters that do not account for the impact of COVID–19 on affected patients. We believe that this misalignment would produce distorted measure results and potentially yield biased CMS PSI 90 measure results among hospitals highly impacted by the COVID–19 PHE. Therefore, for the FY 2023 program year we proposed to not calculate measure results for CMS PSI 90, to not provide the measure results for the CMS PSI 90 measure to hospitals via their hospital-specific reports (HSRs), and to not publicly report those measure results on the Care Compare tool hosted by Health and Human Services and the Provider Data Catalog. We refer readers to section V.J.3.c.(1). and (2) of this final rule where we discuss the impact of the COVID–19 PHE on the CMS PSI 90 measure and a technical update to the measure specifications to risk-adjust for COVID–19 diagnoses.

For the remaining measures, specifically the CDC NHSN HAI measures, we would use the previously finalized applicable periods [300] to calculate measure results (that is, SIRs for each of the CDC NHSN HAI measures) the FY 2023 program year. We would use those measure results in feedback reports to hospitals and as part of program activities, fulfilling our obligation under section 1886(p)(5) of the Act to provide confidential reports to applicable hospitals with information on their performance on measures with respect to hospital-acquired conditions. Consumers may continue to access information on hospital performance with regards to hospital-acquired conditions through several channels, including the Care Compare tool hosted by Health and Human Services, currently available at *https://www.medicare.gov/care-compare*, the Provider Data Catalog, available at *https://data.cms.gov/provider-data/*.

Ultimately, we stated in the proposed rule that if we finalize our proposals, all hospitals would receive a Total HAC Score of zero, and no hospitals would receive a penalty for FY 2023. We would report the measure scores of ''N/A'', Total HAC Score of zero and payment reduction indicators of ''no penalty'' for all hospitals for the FY 2023 program year after confidentially reporting via HSRs and a 30-day preview period and then publicly reporting on the Care Compare tool hosted by Health and Human Services and the Provider Data Catalog. For the five CDC NHSN HAI measures, we would also report the measure results, both via HSRs and public reporting methods. For the CMS PSI 90 measure results, we would not calculate or report on the measure results and would indicate 'N/A' in confidential and public reporting. We would resume calculating measure scores in the FY 2024 program year, as discussed in section V.J.2.b.(3). of this final rule.

In determining how to address the impact of the COVID–19 PHE on hospital performance and calculating Total HAC Scores for FY 2023, we also considered suppressing some CY 2021 quality measure data as an alternative to suppressing all measures. Under this alternative, we considered suppressing the CY 2021 data for the CLABSI, CAUTI, and MRSA measures on the basis that performance on those measures continued to be affected by the COVID–19 PHE. We considered scoring hospitals based solely on their performance on SSI, CDI, and CMS PSI 90; however, we had concerns about running the HAC Reduction Program on only half of the program's measures as this may result in measure scores that are significantly better or worse than in immediately preceding years. In addition, a Total HAC Score based on only three program measures would be less reliable, with more random noise in identification of bottom quartile hospitals, than a score based on six program measures. Therefore, we believe it is appropriate to suppress all five CDC NSHN HAI measures and the CMS PSI 90 measure from the calculation of measure scores and Total HAC Scores for the FY 2023 program year.

We also considered making no modifications to the program and suppressing no additional measure data

[300] In the FY 2022 IPPS/LTCH PPS final rule, we finalized that the applicable periods for the FY 2023 HAC Reduction Program are for the CDC NHSN HAI measures the 12-month period from January 1, 2021 through December 31, 2021.

from the FY 2023 Total HAC Scores rather than extending the measure suppression policy. As discussed, when considering this approach in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45305), this alternative would be operationally easier to implement, but would mean assessing participating hospitals using quality measure data that have been distorted by the COVID–19 PHE without additional adjustments to the measure. Additionally, given the geographic disparities in the COVID–19 PHE's effects, this policy could place hospitals in regions that were hit harder by the pandemic in CY 2021 at a disadvantage compared to hospitals in regions that were more heavily affected in CY 2020. Ultimately, we believe that our proposal to suppress all measures from the FY 2023 HAC Reduction Program more fairly addresses the impact of the COVID–19 PHE for participating hospitals.

Finally, we considered reusing a previous fiscal year's applicable period to serve as the applicable period for FY 2023. Although this option would enable us to continue operating the program, it has the disadvantage of double penalizing hospitals that were in a prior fiscal year's worst performing quartile even if the hospital had implemented policy and operational changes to improve their performance in future program years. Under this option, no new quality data would be used to inform hospitals or drive quality improvement.

We continue to be concerned about the pandemic, but are encouraged by the development and rollout of prevention techniques like COVID–19 vaccinations and treatment for those diagnosed with COVID–19. Our measure suppression policy focuses on a short-term, equitable approach during this unprecedented PHE, and was not intended for indefinite application. We also recognize that measure performance for some measures may not immediately return to levels seen prior to the PHE, particularly for the CDC NHSN HAI measures for which we do not receive patient-level data. Additionally, we wanted to emphasize the long-term importance of value-based care and incentivizing quality care tied to payment. The HAC Reduction Program is an example of our long-standing effort to link payments to healthcare quality in the inpatient hospital setting payment.[301] Therefore, we note that our goal is to continue resuming the use of measure data for the purposes of scoring and payment adjustment beginning with the FY 2024 program year.

We understand that the COVID–19 PHE is ongoing and unpredictable in nature, however, we believe that CY 2022 has a more promising outlook in the fight against COVID–19. As we enter the third year of the pandemic, healthcare providers and systems have gained experience managing the disease, surges of COVID–19 infection, and adjusting to supply chain fluctuations.[302] In CY 2022 and the upcoming years, we anticipate continued availability and increased uptake in the use of vaccinations and the associated boosters,[303] including vaccination for children ages 5–11, who were not eligible for vaccination for the majority of 2021 and of whom only 36 percent had received at least one dose as of June 29, 2022.[304] [305] Additionally, the FDA issued emergency use authorizations (EUAs) for the first oral antiviral COVID–19 pill on December 22, 2021, and later approved a second the following day, expanding access to at-home COVID–19 treatment options.[306] [307] Finally, the Biden-Harris Administration has mobilized efforts to distribute home test kits,[308] N–95 masks,[309] and increase COVID–19 testing in schools,[310] providing more treatment and testing to the American people. Given these developments, we will continue to assess the impact of the PHE on measure data used for the HAC Reduction Program.

We invited public comments on our proposals. We received a large volume of input from the public regarding these proposals. We first address the comments related to our proposal to suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score, thereby not penalizing any hospital under the FY 2023 HAC Reduction Program, for the purposes of scoring and payment. Next, we address the proposal to suppress calculation and public reporting of measure results for CMS PSI 90 for FY 2023.

Comment: Many commenters supported the proposal to suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score, thereby not penalizing any hospital under the FY 2023 HAC Reduction Program. Several commenters agreed that this policy would help ensure hospitals are not penalized for conditions beyond the control of hospitals and providers that may negatively impact hospital performance. Several supported the proposal due to the significant impact of the COVID–19 PHE on quality measures. A few commenters noted that this proposed policy would provide important relief and stability for providers, especially rural providers, regarding compliance concerns so they can focus on the unique challenges of providing care during the COVID–19 PHE. Several commenters supported the proposal because it addresses the significant

[301] CMS has also partnered with the CDC in a joint Call to Action on safety, which is focused on our core goal to keep patients safe. Fleisher et al. (2022). *New England Journal of Medicine.* Article available here: *https://www.nejm.org/doi/full/10.1056/NEJMp2118285?utm_source=STAT+Newsletters&utm_campaign=8933b7233e-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-8933b7233e-151759045*.

[302] Schneider, E. et al. (2022). *The Commonwealth Fund.* Responding to Omicron: Aggressively Increasing Booster Vaccinations Now Could Prevent Many Hospitalizations and Deaths. Available at: *https://www.commonwealthfund.org/blog/2022/responding-omicron.*

[303] Schneider, E. et al. (2022). *The Commonwealth Fund.* Responding to Omicron: Aggressively Increasing Booster Vaccinations Now Could Prevent Many Hospitalizations and Deaths. Available at: *https://www.commonwealthfund.org/blog/2022/responding-omicron.*

[304] KFF, Update on COVID–19 Vaccination of 5–11 Year Olds in the U.S., *https://www.kff.org/coronavirus-covid-19/issue-brief/update-on-covid-19-vaccination-of-5-11-year-olds-in-the-u-s/.*

[305] American Academy of Pediatrics. (2022). Summary of data publicly reported by the Centers for Disease Control and Prevention. Available at: *https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-vaccination-trends/.*

[306] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID–19. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19.*

[307] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID–19 in Certain Adults. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain#:~:text=Today%2C%20the%20U.S.%20Food%20and,progression%20to%20severe%20COVID%2D19%2C.*

[308] The White House. (2022). Fact Sheet: The Biden Administration to Begin Distributing At-Home, Rapid COVID–19 Tests to Americans for Free. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/.*

[309] Miller, Z. (2021). *The Washington Post.* Biden to give away 400 million N95 masks starting next week. Available at: *https://www.washingtonpost.com/politics/biden-to-give-away-400-million-n95-masks-starting-next-week/2022/01/19/5095c050-7915-11ec-9dce-7313579de434_story.html.*

[310] The White House. (2022). FACT SHEET: Biden–Harris Administration Increases COVID–19 Testing in Schools to Keep Students Safe and Schools Open. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/12/fact-sheet-biden-harris-administration-increases-covid-19-testing-in-schools-to-keep-students-safe-and-schools-open/.*

deviation in national performance across all program measures due to the COVID–19 PHE. Many commenters supported the proposal due to the belief that the COVID–19 PHE negatively impacted hospitals and patients through a number of factors including quickly changing clinical practices, operational changes, increased clinical acuity, staffing and supply shortages, and care capacity concerns. Several commenters supported the proposal because of the disproportionate impacts of the COVID–19 PHE on hospital performance given geographic and temporal variation in surges of cases. A commenter supported the proposal due to the belief that this will provide hospitals more time to focus on training and education rather than public reporting of measure scores. A commenter supported the proposal due to the belief that this will help alleviate hospital administrative burden.

Response: We thank commenters for their support. We agree that the proposed suppression, scoring, and payment policies for the FY 2023 program year were developed using data-driven approaches and are intended to balance the importance of patient safety through transparency and public reporting while allowing hospitals to maintain access to care and focus on providing quality health care to patients during the COVID–19 PHE. Additionally, we agree that suppressing these measures for scoring and payment purposes will ensure hospitals are not penalized for impacts outside of their control and note that hospitals will still be required to report measure data for the five CDC NSHN HAI measures and CMS PSI 90 will be calculated through claims data, so hospital administrative burden will remain unchanged.

Comment: A few commenters expressed support for the proposal to suppress the HAI measures from scoring and payment because they believe that CMS could not feasibly use either risk adjustment or exclusions to account for COVID–19 diagnoses in calculating performance.

Response: We thank commenters for their support and agree that the HAI measures cannot be risk-adjusted due to the reasons described in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28449 through 28450) and in this final rule.

Comment: Many commenters did not support the proposal to suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score. Many commenters recommended that instead of finalizing the proposal to not score or penalize hospitals for their performance, CMS should penalize the worst performing hospitals to incentivize quality improvement. A few commenters requested that CMS explore the authority to provide payment bonuses for hospitals to create a reward for improved patient care. Many commenters did not support the proposal due to the belief that not instituting payment penalties would not hold hospitals accountable for care delivered to patients. Many commenters did not support the proposal because they believe that suspending payment reduction would be poor financial stewardship of the Medicare Trust Fund and ultimately not help beneficiaries.

Response: We thank the commenters for their feedback. Throughout the COVID–19 PHE, we have prioritized access to safe, comprehensive healthcare, and we continue to make patient safety our primary concern. As part of this dedicated commitment to patient safety, we ensure public access to the highest quality data regarding the performance of health care facilities. We continue to collect and closely monitor performance to ensure safety, and will continue to share that data with the public. We understand commenters' concerns; though we recognize that some hospitals have maintained strong performance on measures throughout the COVID–19 PHE, we do not believe it is appropriate to penalize any hospitals based on measure data that we believe were distorted by the COVID–19 PHE, the impacts of which were geographically and temporally varied during 2021, and, thus, would not ensure an accurate and reliable national comparison of performance on hospital safety for penalty purposes. Meanwhile, we note the HAC Reduction Program statute does not grant the authority to award payment bonuses or incentive payments to hospitals with favorable performance and measure outcomes. Interested parties can view the HAC Reduction Program statute at § 412.172 for more details on the payment requirements. Additionally, we note that the suppression, scoring, and payment policies for the FY 2023 program year were developed using data-driven approaches that are intended to balance the importance of patient safety through transparency and public reporting while allowing hospitals to maintain access to care and focus on providing quality health care to patients during the COVID–19 PHE.

Comment: A commenter expressed concern over the misalignment of the Measure Suppression Factors used across the Hospital VBP and HAC Reduction Programs for the HAI measures.

Response: We appreciate the commenter's concern regarding consistency. To promote alignment across our value-based purchasing programs, in both the Hospital VBP and HAC Reduction Programs, we proposed to suppress three of the five CDC NSHN HAI measures (CLABSI, CAUTI, and MRSA) under Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; to suppress the SSI measure under Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in patient case volumes; and to suppress the CDI measure under Measure Suppression Factor 3, rapid or unprecedented changes in clinical guidelines, care delivery or practice, related protocols, or equipment or diagnostic tools or materials. We applied these measure suppression factors with both program-specific considerations in mind as well as cross-program alignment. We continue to believe that suppressing the HAI measures under the HAC Reduction Program and the Hospital VBP Program for purposes of scoring and payment will provide flexibility for providers to focus on delivering quality of care to patients during the COVID–19 PHE. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45301 through 45304) for more information on the HAC Reduction Program's measure suppression factors and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45266 through 45269) for more information on the Hospital VBP Program's measure suppression factors.

Comment: Many commenters recommended that we not suppress future measures without seeking public comment which gives the public an opportunity to provide feedback.

Response: We appreciate the commenters' recommendation. Consistent with our previously finalized measure suppression policy in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45301 through 45304), we intend to provide interested parties with the opportunity to comment on future suppression through the rulemaking process.

Comment: A commenter did not support the proposal to suppress the HAI measures from scoring and payment and recommended that we evaluate whether the HAC Reduction Program is sufficiently committed to ensuring a deeply embedded safety culture.

Response: We thank the commenter for sharing their input, and we agree on the importance of safety culture. We also believe building a more resilient health care system is necessary to avoid future threats to patient safety.[311] Specifically, as to the use of 2021 HAI data for assessing HAC Reduction Program penalties, based on data analyses by the CDC, we believe that suppressing the HAI measure for the FY 2023 program year offers hospitals and health systems the flexibility to focus on delivery of care while also accounting for the changing conditions during a PHE that are beyond hospitals' control. In addition, we are committed to the continued collection, reporting, and public availability of the HAI measure data, focusing on transparency, upholding quality care, and helping patients make informed decisions about their care. As we note previously, our goal is to resume the use of 2022 HAI measure data for scoring and payment adjustment purposes beginning with the FY 2024 program year as we believe that 2022 has a more promising outlook in the fight against COVID–19 as we enter the third year of the pandemic.

Comment: Many commenters supported our proposal to continue to publicly and confidentially report HAI measure results. Several commenters supported our proposal because they believe it would promote transparency in reporting of HAI measure data to help interested parties understand the healthcare landscape and the impact of the COVID–19 PHE. A few commenters supported our proposal because of their belief that the public access to the HAI data would allow them to make informed decisions about care. A commenter supported our proposal and recommended that we provide hospitals the option to opt-in to public reporting of the HAI measures.

Response: We thank the commenters for their support and agree that it is important for the public to have access to the HAI measure data to continue to make informed health care decisions. As noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28448) and in this final rule, we intend to publicly report HAI measure results with appropriate caveats that explain that performance information has been impacted due to the COVID–19 PHE. We continue to place significant value on being as transparent as possible with the performance information that we collect, and we will make clear with caveats that performance information was affected by the COVID–19 PHE.

We disagree with the commenter's suggestion to allow hospitals the option to opt-in to public reporting. We believe this may cause greater confusion and would provide an incomplete picture of the impact of COVID–19 on performance data since mostly only hospitals that performed well might choose to opt-in. Additionally, we believe that providing transparent performance information to the public throughout the COVID–19 PHE and beyond is a priority, and we do not believe publicly reporting suppressed measure data places additional burden on providers above the processes providers already have in place that are used to collect and report the data to CMS and the CDC. We encourage hospitals to continue focusing on providing quality care, and we believe that the continued collection and public reporting of performance information can be a useful tool to inform future quality improvements for health care providers.

Comment: Many commenters did not support suppression of the CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score for the FY 2023 HAC Reduction Program out of concerns relating to access to publicly reported measure data. Many commenters expressed their belief that the proposal to suppress the CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score would prevent patients from making informed decisions on where to receive care, especially those at high risk for the measure. Similarly, several commenters did not support the proposal because they believe it violates CMS' commitment to public safety by not granting the public access to hospital performance data. Several commenters stated that the proposal would not hold hospitals accountable for patient safety and the level and quality of care delivered. A few commenters stated that suppressing the HAI measures would create the perception that the government is not disclosing information, reducing public trust and transparency.

Response: We thank the commenters for expressing their concerns. As discussed in section V.J.2.b.(2)., we wish to clarify that we are continuing to publicly report the CDC NSHN HAI measure results—the suppression proposal related to the five CDC NHSN HAI measure results was limited to suppression of the measures from the calculation of measure scores and the Total HAC Score for purposes of assessing HAC Reduction Program penalties for FY 2023. As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28448) and section V.J.2.b.(2). of this final rule, we intend to publicly report the suppressed CDC NHSN HAI measure data with appropriate caveats, as we recognize the importance of transparency, promoting public trust, and empowering individuals to make data-informed decisions using the publicly reported HAI measure data. We will also continue to provide confidential feedback reports to hospitals through the previously established processes, including the information available to hospitals via the CDC's National Healthcare Safety Network, as part of program activities to ensure that hospitals are made aware of the changes in performance rates that we observe. We believe that continuing to make the data publicly available ensures that hospitals are still held accountable for their quality of care as consumers decide where to obtain care based on the publicly available data on hospital performance.

Comment: A commenter did not support HAI suppression out of concern that we might have difficulty adhering to, interpreting, and operationalizing the Measure Suppression Factors, given the ever-changing landscape. A commenter did not support HAI suppression, believing that being unable to determine the causes of changes in HAI rates is not a rationale for suppression. A commenter did not support HAI suppression, stating that the rationale exceeds program authority and recommending that CMS retract its stated rationale for the suppression of NHSN CDC HAIs in this final rule.

Response: We appreciate the concern surrounding the operationalizing of the measure Suppression Factors. We believe that, in the face of evolving circumstances of the COVID–19 PHE, the level of detail in the Suppression Factors, which were developed and finalized in the FY 2022 IPPS/LTCH PPS final rule to specifically address challenges that arose due to the COVID–19 PHE, is sufficient and applicable in suppressing the HAI measures. In deciding which measures to suppress, and as discussed in the proposed rule and this final rule, we examined each measure and determined that the evidence showed significant deviation in the individual measure performance data associated with the COVID–19 PHE and/or a low reporting volume. Additionally, the COVID–19 PHE in

[311] Fleisher et al. (2022). ''Health Care Safety during the Pandemic and Beyond—Building a System That Ensures Resilience''. *New England Journal of Medicine.* Article available here: *https://www.nejm.org/doi/full/10.1056/NEJMp2118285?utm_source=STAT+Newsletters&utm_campaign=8933b7233e-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-8933b7233e-151759045.*

2021 presented unique and unprecedented experiences that challenged hospitals in new ways beyond their control. We believe that it would be unfair to score or penalize hospitals through payment during these unique challenges, thus warranting the use of Measure Suppression Factors. We do not anticipate implementing the Measure Suppression Factors in other instances outside of such an unprecedented and unique circumstance as the COVID–19 pandemic.

Comment: A commenter questioned whether we would be publicly reporting the HAI measure results in the aggregate form (that is, deidentified).

Response: We appreciate the commenter's question. CDC collects data for the HAI measures at the ward level rather than the patient level, and then provides aggregate results at the individual hospital CCN level. Therefore, the data reported publicly will not have patient identifiable information, but will be identifiable by hospital aggregated to the same CCN.

Comment: A commenter did not support publicly reporting the HAI measure results until the HAI measures can be risk adjusted for COVID–19.

Response: We appreciate the commenter's recommendation. However, due to the nature of the HAI measure data being collected at the ward level rather than the patient level, we cannot feasibly risk adjust or exclude for COVID–19 diagnoses in calculating hospital performance on the HAI measures. Additionally, we believe the HAI rates could potentially still be impacted even with COVID–19 risk adjustment because pandemic-related hospital staffing and resource issues affect a hospital's entire patient population. We continue to place significant value on being as transparent as possible with the performance information that we collect, and we will make clear with caveats that performance information was affected by the COVID–19 PHE.

Comment: A few commenters recommended that the HAI measures continue to be suppressed until the end of the COVID–19 PHE. A few commenters recommended that we continue to evaluate the impact of the COVID–19 PHE on the data as the PHE subsides. A commenter recommended that we suppress CY 2020 and CY 2021 data from the HAI measure to address the impact of the COVID–19 PHE. A few commenters expressed concern about publicly reporting the HAI measure results because the data will be distorted and of little value to the public. Several commenters believed that publicly reporting the data would cause confusion or be misinterpreted by consumers due to the impacts of the COVID–19 PHE outside of facilities control. A commenter recommended that we delay public reporting of the HAI measures so that we can evaluate how to best communicate the impacts of the COVID–19 PHE to consumers.

Response: We thank the commenters for their recommendations and will continue to monitor the PHE's ongoing effects carefully on the measures within the HAC Reduction Program. In the September 2, 2020 IFC,[312] we finalized exclusion of data submitted regarding care provided during the first and second quarters of CY 2020 from calculation of scoring and payment adjustments in the HAC Reduction Program. In the FY 2022 IPPS/LTCH final rule (86 FR 45307 through 45307), we finalized suppression of the third and fourth quarters of CY 2020 CDC NSHN HAI data for purposes of scoring and payment adjustments. In the FY 2023 IPPS/LTCH proposed rule (87 FR 28446 through 28450), we proposed to suppress CY 2021 CDC NHSN HAI measure data from the FY 2024 HAC Reduction Program for purposes of scoring and payment adjustments. Therefore, we have suppressed CY 2020 and CY 2021 HAI measure data from the HAC Reduction Program for scoring and payment purposes.

We understand commenters' concerns with publicly reporting measure data that were suppressed for purposes of calculating the measure scores and Total HAC Score. However, we disagree that publicly reporting suppressed measure data is not useful for consumers and interested parties. We continue to place significant value on being as transparent as possible with the performance information that we collect, and we will make clear with caveats that that performance information was affected by the COVID–19 PHE. We encourage hospitals to continue focusing on providing quality care, and we believe that the continued collection and public reporting of performance information can be a useful tool to inform future quality improvements for health care providers.

[312] Centers for Medicare and Medicaid Services. (2020). Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19. Available at: *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-qualityreporting-and-value-based-purchasingprograms.pdf.*

Comment: Many commenters supported the proposal to suppress the calculating and reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Several commenters supported the proposal because they believe the impacts of the COVID–19 PHE affected the accuracy of the data. Several commenters supported the proposal due to the potential for distorted measure results because of discrepancies in the reference and applicable periods among hospitals impacted by COVID–19. A few commenters supported the proposal, noting their belief that because hospitals are seeing COVID–19 hospitalizations increase again, hospital care will likely be substantially impacted by these trends for the foreseeable future. A commenter recommended suppressing CMS PSI 90 through at least Q2 2022.

Response: We thank the commenters for their support, and we understand and acknowledge commenter's concerns regarding the impact of the COVID–19 PHE on the CMS PSI 90 measure. In light of the comments received and in alignment with our continued commitment to transparency, we are not finalizing our proposal to suppress the calculating and public reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Additional detail on how the measure will be adjusted to exclude patients with a diagnosis of COVID–19 is discussed at the end of this section in this rule. In public and confidential reporting, we intend to annotate measure data to indicate that performance was affected by the COVID–19 PHE. We thank the commenters for their recommendations, and we will continue to monitor the PHE's ongoing effects carefully.

Comment: A few commenters expressed support for the proposal to suppress the calculating and public reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program, noting that consumers may not fully understand the caveats on Care Compare and that third party organizations may misuse the data. A commenter expressed their belief that public reporting is not of any value, even with the appropriate caveats on data limitations.

Response: We appreciate the commenters' support and concerns. We have always believed that public reporting of measure data is an invaluable tool for patients, providers, and the public. Public reporting of measure data fosters transparency and provides safety information to the public in order to assist them with their healthcare decisions. While we proposed to not calculate or publicly

report the CMS PSI 90 measure unadjusted for any impacts of COVID–19, since the publication of the proposed rule, we have been able to determine a method for excluding patients with a diagnosis of COVID–19 that will allow us to calculate and publicly report valid and reliable measure results. Therefore, based on this measure adjustment and stakeholder support for continued public reporting, we are not finalizing our proposal to suppress the calculating and public reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. We believe that publicly reporting the CMS PSI 90 measure data with these adjustments is of value and an important step in providing transparency and upholding quality of care and safety for consumers. Additional detail is discussed later in this rule.

Comment: A few commenters recommended three methods we could employ to preserve the integrity of the CMS PSI 90 measure for the FY 2023 program year including: applying a measure exclusion for COVID–19 diagnosis, excluding cases with a COVID–19 diagnosis 12 months prior to admission, or including a COVID–19 diagnosis at admission variable in the risk adjustment methodology. A commenter recommended that for version 12 of the CMS PSI 90 software CMS extend the applicable period to include more data from 2021 to increase the number of hospitals measured and increase measure reliability. Several commenters recommended that we should continue to report CMS PSI 90 measure data on Care Compare with the caveat that the values are not adjusted for COVID–19 diagnosis.

Response: We appreciate commenters' recommendations regarding alternatives to suppressing CMS PSI 90 measure results for the FY 2023 program year. We note that for the FY 2023 program year, we will be applying an exclusion to CMS PSI 90 for patients with a diagnosis of COVID–19 as a few of the commenters suggested. Since the publication of the proposed rule, we have been able to determine a method for excluding patients with a diagnosis of COVID–19 that will allow us to calculate and publicly report valid and reliable measure results. We refer readers to section V.J.3.c.(2) of this final rule for more detail on the updates to the measure specifications being made for the FY 2024 to risk-adjust for COVID–19 diagnoses (in any position) present on admission. We note that risk adjustment details are released to the public when each version of the software is completed and made available. The Risk Adjustment methodology report will be posted on the QualityNet website for CMS PSI 90 Resources at *https://qualitynet.cms.gov/inpatient/measures/psi/resources*. The risk adjustment methodology is part of the routine annual process to update the CMS PSI 90 measure, where the measure developer will submit an annual update to NQF that includes updates to the risk adjustment model.[313] We appreciate the commenters' recommendation to extend the applicable period to include more data from 2021 to increase the measure reliability and will consider it as we continue to assess the impact of the COVID–19 PHE on our measure data.

Comment: A number of commenters did not support the proposal to suppress the calculating and public reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Many commenters did not support the proposal because they believe the data should remain publicly available in order for patients to make informed decisions on where to receive care. Several commenters did not support the proposal because they believe it would reduce the usefulness of the data displayed on Care Compare.

Response: We thank the commenters for sharing their concerns. As discussed, since the publication of the proposed rule, we have been able to determine a method for excluding COVID–19 patients from program calculations that will allow us to calculate and publicly report valid and reliable measure results. This exclusion method uses fields available in the claims form to identify patients with a diagnosis of COVID–19. After identifying these patients, we will exclude them from our measure calculation for our CMS PSI 90 measure. We agree that we should continue publicly reporting the CMS PSI 90 measure so patients can make informed decisions about where they receive care. Ultimately, we believe that publicly reporting this measure data with these exclusions is of value and an important step in providing transparency and upholding quality of care and safety for consumers. In light of the comments received and in alignment with our continued commitment to transparency, we are not finalizing our proposal to suppress the calculating and public reporting of CMS PSI 90 measure results for the FY 2023 program year. Additional detail is discussed at the end of this section in this rule. We intend to confidentially report and publicly report the measure results, annotated to identify where performance was affected by the COVID–19 PHE.

Comment: Many commenters did not support the proposal to suppress the calculating and public reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program because they believe the proposal violates the public trust in both CMS and the medical community and also reduces transparency in the Medicare program. Commenters also suggested that this proposal could erode patient safety infrastructure and ultimately hurt patients. Many commenters did not support the proposal and expressed concern about public awareness of potentially increasing rates of medical errors and infections. A few commenters did not support the proposal due to the belief that suppression of these data from reporting will not improve staffing shortages or clinical training, which have been critical contributors to poor hospital performance on the measures.

Response: We thank the commenters for sharing their concerns. As discussed, since the publication of the proposed rule, we have been able to determine a method for excluding COVID–19 patients from program calculations that will allow us to calculate and publicly report valid and reliable measure results. This exclusion method uses fields available in the claims form to identify patients with a diagnosis of COVID–19. After identifying these patients, we will exclude them from our measure calculation for our CMS PSI 90 measure. We agree with commenters that we should continue publicly reporting measure data for CMS PSI 90. Therefore, we note, that after consideration of the public comments we received, we are not finalizing our proposal to suppress the calculating and public reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Additional details are discussed later in this section of the rule. Ultimately, we believe that publicly reporting suppressed measure data is an important step in providing transparency and upholding quality of care and safety for consumers.

We also believe that publicly reporting CMS PSI 90 will help enforce patient safety infrastructure and benefit the patient-provider relationship. Additionally, we believe that confidentially reporting these measure data will help empower hospitals to better understand their performance and make improvements to staffing, education, and training.

[313] National Quality Forum. (2022). *Maintenance of NQF-Endorsed Performance Measures.* Available at: *https://www.qualityforum.org/measuring_performance/endorsed_performance_measures_maintenance.aspx.*

Comment: Many commenters did not support the proposal to suppress the calculating and public reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program due to the belief that there is no other publicly available source for data on the complications included in PSI 90 and if we do not publicly report this data interested parties will not have access to the data to inform their decisions. Many commenters did not support the proposal because they believe that public reporting of CMS PSI 90 measure data helps interested parties understand the patient safety landscape and prevent more adverse events from occurring. Many commenters did not support the proposal due to the belief that public reporting of the CMS PSI 90 measure helps employers and health plans analyze care delivery and promote robust health plan networks. Several commenters recommended that CMS report CMS PSI 90 measure data so that regulators and researchers can learn from the COVID–19 PHE and develop an action plan to improve hospital performance. Many commenters recommended that CMS report the PSI 90 measure data to align with the recommendations focused on expanding focus and resources on patient safety contained in the 2018 Office of the Inspector General Report on Adverse Events in Hospitals.[314]

Response: We agree with the commenters concerns and recommendations regarding the public and confidential reporting of the CMS PSI 90 measure and recognize that interested parties should have access to this data to make data-informed decisions. Therefore, we note, that since we were able to determine a method for excluding COVID–19 patients from program calculations that will allow us to calculate and publicly report valid and reliable measure result, we are not finalizing our proposal to suppress the calculating and reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. This exclusion method uses fields available in the claims form to identify patients with a diagnosis of COVID–19. After identifying these patients, we will exclude them from our measure calculation for our CMS PSI 90 measure. Additional detail is discussed at the end of this section in this rule. We encourage hospitals to continue maintaining access and focusing on providing quality care, and we believe that the continued collection, analysis, and public reporting of patient safety performance information can be a useful tool to inform future quality improvement for health care systems, maintain focus on patient safety, and ultimately improve patient care.

Comment: Many commenters did not support the proposal to suppress the calculating and public reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program due to their belief that CMS PSI 90 data provides essential information about significant health care disparities that exist in patient safety. These commenters stated that not reporting on the CMS PSI 90 measure will perpetuate these health inequities and prevent quality improvement efforts to decrease disparities. Many commenters noted that the suppression of the CMS PSI 90 measure would impede decision-making specifically for those populations that are high-risk for adverse patient safety events.

Response: We share the commenters' concern about health equity and high-risk patients and note that as discussed, we are not finalizing our proposal to suppress the calculating and reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Additional detail is discussed at the end of this section in this rule.

We believe that by continuing to publish the data for these measures, in a way that is accessible to consumers and researchers, patients can make informed decisions about their care. Additionally, we refer readers to section IX.B. focused on our Request for Information, Overarching Principles for Measuring Quality Disparities Across CMS Quality Programs, where we requested information on healthcare quality disparities in hospital quality and value-based purchasing programs, which will inform our Equity Plan for Improving Quality in Medicare. We are committed to promoting health equity through our CMS National Quality Strategy [315] and CMS Framework for Health Equity 2022–2032,[316] which focuses on advancing health equity and addressing the health disparities that underlie our health system.

Comment: A few commenters did not support the proposal to suppress CMS PSI 90 because they believe that we did not justify suppression based on any of the measure suppression factors in the FY 2023 IPPS/LTCH PPS proposed rule.

Response: We acknowledge the commenters' concerns, however, in the FY 2023 IPPS/LTCH proposed rule, we discussed our rationale that our analysis of the CMS PSI 90 measure suggested that comparability of performance on the measure has also been impacted by the PHE and our analysis found that there was a decrease in volume across all component PSI measures, especially those related to surgical procedures. We stated that this rationale falls under Measure Suppression Factor 4, ''significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix'' (87 FR 28446 through 28447; and 28452). Additionally, we stated that the CMS PSI 90 reference period does not include data affected by the COVID–19 PHE and the applicable period does include such data. We stated that this misalignment would produce distorted measure results and potentially yield biased CMS PSI 90 measure results among hospitals highly impacted by the COVID–19 PHE (87 FR 28448). We believe we have appropriately applied the Measure Suppression Factors in this rulemaking to address the impacts of the COVID–19 PHE on the HAC Reduction Program measures.

Comment: A few commenters did not support the proposal to suppress CMS PSI 90 and not calculate or report CMS PSI 90 measure results for the FY 2023 HAC Reduction Program due to their belief that the proposal does not align with our priorities outlined in the 2022 CMS Strategic Framework.[317] A few commenters did not support the proposal because they believed that hospitals do not want outdated data to represent their performance especially since some facilities have made quality improvements during the COVID–19 PHE.

Response: We acknowledge the commenters' concerns regarding alignment with our 2022 CMS Strategic Framework as well as outdated measure data representing hospital performance. We note, however, that after consideration of the public comments we received, we are not finalizing our proposal to suppress the calculating and reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Additional detail is discussed at the end of this section in this rule. We

[314] Department of Health and Human Services, Office of the Inspector General. (2018). *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018.* Available at: *https://oig.hhs.govAd/oei/reports/OEI-06-18-00400.asp.*

[315] Centers for Medicare and Medicaid Services. (2022). CMS Strategic Plan: Health Equity. Available at: *https://www.cms.gov/files/document/cms-national-quality-strategy-fact-sheet-april-2022.pdf.*

[316] Center for Medicare and Medicaid Services. (2022). CMS Framework for Health Equity 2022–2032. Available at: *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

[317] Centers for Medicare and Medicaid Services. (2022). *2022 CMS Strategic Framework.* Available at: *https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.*

strongly believe that publicly reporting these data aligns with our Strategic Plan and will balance our responsibility to provide transparency to consumers while ensuring hospitals are not unfairly scored or penalized. Also, since we will calculate updated measure results for CMS PSI 90, hospitals will not have outdated information representing performance on the measure.

Comment: A commenter recommended that if the CMS PSI 90 measure is suppressed from the FY 2023 HAC Reduction Program that we instead report the PSI 03 measure as a stand-alone measure because this will help maintain hospital focus on pressure ulcers and injuries and would lead to better reporting and improved patient care since the measure has a sole focus.

Response: We agree with the commenter on the importance of measuring pressure ulcers and injuries which is the intent of the PSI 03 measure. Because we are not finalizing the proposal to suppress the calculating and public reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program, data on pressure ulcers and injuries will continue to be reported publicly and confidentially as part of the PSI 90 measure results. We also note that PSI 03 will be publicly available in the Provider Data Catalog.

Comment: Many commenters recommend that we continue to report CMS PSI 90 data and publish previous CMS PSI 90 data since it is important that interested parties have access to all previous CMS PSI 90 data from CY 2019 and past years. A few commenters recommended that we consider continuing to publicly report the CMS PSI 90 measure using hospital's pre-pandemic data. A few commenters recommended that we report CMS PSI 90 measure data on the Provider Data Catalog since this is valuable data for health systems to learn from but not on Care Compare because the data impacted by the COVID–19 PHE should not be used for scores, grades, or ratings.

Response: We acknowledge the commenters' recommendations regarding public reporting of CMS PSI 90. We note, that after consideration of the public comments we received and because we identified a method for excluding COVID–19 patients from program calculations that will allow us to calculate and publicly report valid and reliable measure results, we are not finalizing our proposal to suppress the calculating and reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Although we will not calculate or report CMS PSI 90 measure results for use in the HAC Reduction Program scoring calculations for the program year, we will still calculate and publicly report the CMS PSI 90 measure displayed on the main pages of the Care Compare tool hosted by HHS after confidentially reporting these results to hospitals via CMS PSI 90-specific HSRs and a 30-day preview period. We will also be reporting these results on the Provider Data Catalog. We strongly believe that publicly reporting these data will balance our responsibility to provide transparency to consumers while ensuring hospitals are not unfairly penalized.

We acknowledge the commenter's recommendation to continue public reporting of CMS PSI 90 using hospital's pre-pandemic data and understand that hospitals have been impacted by the pandemic. For this reason, for the FY 2023 HAC Reduction Program, we are not assessing payment penalties for hospitals which report HAC Reduction Program measures. This policy in combination with calculating and publicly reporting CMS PSI 90 ensures that interested parties can access the measure data but hospitals are not penalized for the differential effects of the COVID–19 PHE outside of their control.

We also acknowledge the commenters recommendation to report historic CMS PSI 90 data, and note that CMS PSI 90 data is available from the last seven years on the Provider Data Catalog's Data Archive at this website: *https://data.cms.gov/provider-data/archived-data/hospitals*.

Comment: A few commenters recommended that we begin to resume normal reporting of the CMS PSI 90 measure publicly and confidentially when hospitals are less burdened by the impacts of the COVID–19 PHE. A few commenters recommended that we not publicly report PSI 90 measure data but calculate the measure and report the data confidentially so hospitals can gain insight into their performance.

Response: We appreciate the commenters' recommendation to not publicly report CMS PSI 90 until the COVID–19 PHE recedes, and to report the CMS PSI 90 measure confidentially so that hospitals can understand their performance. We note, that after consideration of the public comments we received and because we identified a method for excluding COVID–19 patients from program calculations that will allow us to calculate and publicly report valid and reliable measure results, we are not finalizing our proposal to suppress the calculating and reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Additional detail is discussed at the end of this section in this rule. We will ensure the appropriate caveats are applied to public reporting of the measure so that interested parties understand the data was impacted by the COVID–19 PHE. We also will be confidentially reporting these results to hospitals via CMS PSI 90-specific HSRs so that hospitals can evaluate their performance on the measure.

We reiterate that ensuring patient safety, and access to safe, equitable, quality health care is high priority and a primary concern. We continue to place significant value on being as transparent as possible with the performance information that we collect to support the decision making of consumers, healthcare providers, researcher, and other interested parties. After consideration of the public comments we received, and because since the publication of the proposed rule, we have determined a methodology to exclude COVID–19 patients from the CMS PSI 90 measure that will allow us to calculate and publicly report valid and reliable measure results, we are not finalizing our proposal to suppress the calculating and reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Although we will not calculate or report CMS PSI 90 measure results for use in the HAC Reduction Program scoring calculations for the program year, we will still calculate and report the measure displayed on the main pages of the Care Compare tool hosted by HHS after confidentially reporting these results to hospitals via CMS PSI 90-specific HSRs and a 30-day preview period. We will continue to calculate and report measure results for the five CDC NSHN HAI measures. Further, we are finalizing our proposal to suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and Total HAC Scores for the FY 2023 program year, thereby not penalizing any hospital under the FY 2023 HAC Reduction Program. We thank the commenters for their comments and suggestions, which we will take into consideration when assessing potential future measure reporting and scoring decisions.

(3) Proposal To Suppress CY 2021 CDC NHSN HAI Measure Data From the FY 2024 HAC Reduction Program Year

As described in section V.J.2.b.(1). of this final rule, we previously excluded or suppressed all quarters of CY 2020 data for all the program measures from the calculation of the Total HAC Score, in part, because of concerns about the national comparability of these data and significant deviation in national

performance on the measure compared to historical performance. The exclusion and suppression of those data resulted in a shortened applicable period for the CMS PSI 90 measure for the FY 2024 HAC Reduction Program, specifically the 18-month period of January 1, 2021 through June 30, 2022. The applicable period for the CDC NHSN HAI measures for the FY 2024 program year was unaffected and remained as the 24-month period of January 1, 2021, through December 31, 2022.

As described previously, we continue to be concerned about measure performance and the national comparability of such performance during CY 2021. We therefore are proposing to suppress CY 2021 CDC NHSN HAI data from the FY 2024 HAC Reduction Program under Measure Suppression Factor 1, ''significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years''; and the Measure Suppression Factor 4 subfactor, ''significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix.'' Under current data collection processes for the CDC NHSN HAI measures, we are not able to risk-adjust for or otherwise account for COVID–19 diagnoses and therefore must suppress the CY 2021 data in order to account for COVID–19 diagnoses in the CDC NHSN HAI data. For the FY 2024 program year, the resulting applicable period for CDC NHSN HAI measures would be the 12-month period of January 1, 2022, to December 31, 2022.

To account for the impact of the COVID–19 PHE on CY 2021 data in the CMS PSI 90 measure, we are updating the measure specifications to risk-adjust for COVID–19 diagnoses, as described in section V.J.3.c.(2). of this final rule, beginning with the FY 2024 program year. Our analysis of the COVID–19 PHE impacts on CY 2021 data found that the decrease in volume continued in CY 2021 across nearly all component Patient Safety Indicator (PSI) measures, especially those related to surgical procedures (for which the denominator volume was 8 percent to 45 percent lower in the first two quarters of CY 2021 than in the corresponding quarters of CY 2019). Our analysis also found that unadjusted rates continued to be high in CY 2021 for patients with a COVID–19 diagnosis compared to patients without a COVID–19 diagnosis. We refer readers to section V.J.3.c.(2). for more information about COVID–19 impacts on the CMS PSI 90 measure.

For the CMS PSI 90 measure, the applicable period remains unchanged from January 1, 2021, through June 30, 2022.[318] If finalized, these policies would result in the following applicable periods for FY 2023, FY 2024, and FY 2025 HAC Reduction Programs:

Applicable Periods for FY 2023, FY 2024, and FY 2025 for the HAC Reduction Program		
Fiscal Year	**Measure Set**	**Current Applicable Periods that Resulted from ECE and Measure Suppression Policies**
FY 2023	CDC NHSN HAI	January 1, 2021, through December 31, 2021
	CMS PSI 90	July 1, 2019, through December 31, 2019; and January 1, 2021, through June 30, 2021
FY 2024	CDC NHSN HAI	January 1, 2022, through December 31, 2022
	CMS PSI 90	January 1, 2021, through June 30, 2022
FY 2025	CDC NHSN HAI	January 1, 2022, through December 31, 2023
	CMS PSI 90	July 1, 2021, through June 30, 2023

We invited public comments on this proposal to suppress CY 2021 CDC NHSN HAI Measure data from the FY 2024 HAC Reduction Program.

Comment: Many commenters supported the proposal to suppress the CY 2021 data from the five CDC NHSN HAI measures for the FY 2024 program year. A few commenters supported the proposal due to the belief that suppression of the CY 2021 data from the five CDC NHSN HAI measures would address significant deviation in national performance due to continued disruptions in the health care system and care delivery process caused by the COVID–19 PHE, including staffing and supply shortages. A few commenters supported the proposal due to the belief that it would prevent hospitals from being penalized and incentivized based on measure data impacted by the COVID–19 PHE. A few commenters suggested to monitor the CDC NHSN HAI measures for fluctuations in performance due to the suppression of the CY 2021 data and ensure continued measure reliability.

Response: We thank commenters for their support, and we agree that suppressing the CY 2021 data from these measures will ensure that hospitals are not penalized for the impacts of the COVID–19 PHE on the healthcare delivery system and subsequently the HAI measure data. We will continue to monitor performance in the CDC NHSN HAI measures and will consider any such issues we identify for future rulemaking.

Comment: Several commenters did not support the suppression of the CY 2021 data from the five CDC NHSN HAI measures for FY 2024. A few commenters did not support the proposal due to the belief that suppressing the CY 2021 data from the five CDC NHSN HAI measures would prevent patients from assessing hospital performance and making informed decisions on where to receive care.

Response: We acknowledge the commenters concern about suppression of the CY 2021 data from the CDC NHSN HAI measure for FY 2024. However, we continue to be concerned about measure performance and the national comparability of such performance during CY 2021. Under the current data collection processes for the CDC NHSN HAI measures, we are not able to risk-adjust for or otherwise account for COVID–19 diagnoses and therefore must suppress the CY 2021 data in order to account for COVID–19 diagnoses in the CDC NHSN HAI data.

Further, we understand commenters' concern regarding patients' ability to make informed decisions on where to receive care. We continue to place significant value on being transparent as possible with the performance

[318] For the FY 2025 HAC Reduction Program year, there is no CY 2021 data included in the applicable period for the HAI measures so the applicable period remains unchanged and would be January 1, 2022, to December 31, 2023. For the CMS PSI 90 measure, the applicable period is July 1, 2021, through June 30, 2023. As discussed, to account for the impact of the COVID–19 PHE on CY 2021 CMS PSI 90 measure data, we are updating the measure specifications to risk-adjust for COVID–19 diagnoses.

information that we collect with caveats of the performance information impacted by the COVID–19 PHE. As discussed in section V.J.2.b.(3) of this final rule, for the FY 2024 program year, we will continue to report the measure data for CY 2021, both in confidential reporting via HSR's and public reporting methods on Care Compare, as part of program activities to ensure that consumers and interested parties are able to assess facility performance and quality of care.

Comment: A commenter did not support the proposal because of the concern regarding hospital accountability, asserting that hospitals utilize the data to improve the patient treatment delivery process and eliminate preventable medical error. A commenter believed that despite the impacts from the COVID–19 PHE this emergency only increases the need to collect and measure the HAI measure data. A commenter recommended to continue to report CY 2021 data including notations of mitigating circumstances and data abnormalities.

Response: We thank commenters for expressing concerns regarding holding facilities accountable for the standard and quality of care of services furnished and the urgency of retaining this requirement during the COVID–19 PHE. We agree that the PHE underscored the importance of measuring hospital acquired infections to promote patient safety. We believe that although the collection, monitoring, and public reporting of COVID–19 impacted data with the appropriate caveats is important, such data should not be used to assess hospital performance and utilized for payment determination or penalties. Under current data collection processes for the CDC NHSN HAI measures, we are not able to risk-adjust for or otherwise account for COVID–19 diagnoses, thus we proposed to suppress the CY 2021 data in order to account for COVID–19 diagnoses in the CDC NHSN HAI data. We agree that the HAI measure data should be confidentially reported and made available to facilities to support improvement initiatives within the patient delivery process, and we will report the measure results, both in confidential reporting via HSR's and public reporting methods on Care Compare, to ensure hospitals are made aware of the changes in performance rates that we observe, as discussed in section V.J.2.b.(2) of this final rule.

We thank the commenter for the suggestion to report the CY 2021 data including notations of data abnormalities. As noted in the preamble of the final rule, we intend to publicly report suppressed data with appropriate caveats that explain that performance information has been impacted due to the COVID–19 PHE.

Comment: A commenter questioned if CMS intends to continue the policy of not assessing payment penalties for the FY 2024 program year. Several commenters recommended that we extend this payment and scoring policy to the FY 2024 program year to account for the continued impact of the COVID–19 PHE. A few commenters recommended that CMS provide additional outreach and educational materials to understand the data-related changes and scoring impacts. Another commenter recommended that CMS provide HAI measure scores to hospitals to allow for evaluation of hospital performance.

Response: In the FY 2023 IPPS/LTCH proposed rule (87 FR 28446 through 28450), we did not propose to not assess payment penalties in the FY 2024 program year, but we understand commenters' concerns regarding the impact of the COVID–19 PHE and will ensure that we monitor and evaluate the data to determine if further suppression is warranted in the future. We want to emphasize the long-term importance of value-based care and incentivizing quality care tied to payment. Therefore, we note that our goal is to continue resuming the use of measure data for the purposes of scoring and payment adjustment beginning with the FY 2024 program year. Additionally, we will work to ensure that hospitals and providers receive additional outreach and educational material that clearly communicates the updates and changes to the HAC Reduction Program. Finally, hospitals will be able to evaluate their performance using the HAI measure results that they receive in their Hospital Specific Reports which we will provide for the FY 2023 program year.

Comment: A commenter did not support the proposal due to belief that it would create the perception that the government is not disclosing information, reducing public trust and transparency.

Response: We understand commenters' concerns regarding public reporting of the HAI measure data to promote public trust and transparency. We continue to place significant value on being transparent as possible with the performance information that we collect with caveats of the performance information impacted by the COVID–19 PHE. Therefore, to address challenges in national comparability of these data and to retain transparency with consumers and interested parties, we proposed to suppress the CY 2021 data for program calculations for payment purposes, but continue to report, both in confidential reporting via HSR's and public reporting methods on Care Compare, the five HAI measures for the FY 2024 program year with the resulting applicable 12-month period of January 1, 2022 to December 31, 2022. Under the current data collection processes for the CDC NHSN HAI measures, we are not able to risk-adjust for or otherwise account for COVID–19 diagnoses and therefore we proposed to suppress the CY 2021 data in order to account for COVID–19 diagnoses and ensure that hospitals are not unfairly scored or penalized through payment due to the COVID–19 PHE.

Comment: Many commenters did not support the proposal due to the belief that the program would be heavily reliant on CMS PSI 90 if the CY 2021 data from the CDC NHSN HAI measures are suppressed. A few commenters recommended to include some limited data for the CDC NHSN HAI measures or to suppress all the measures for FY 2024. A few commenters suggested that CMS evaluate the impacts on hospital performance if hospitals are only scored on CMS PSI 90 for the FY 2024 program year.

Response: We understand the commenters' concern about the program being heavily reliant on CMS PSI 90 for FY 2024 due to the proposed suppression of the CY 2021 data for the CDC NHSN HAI measure. However, we disagree that FY 2024 program year performance will be too heavily dependent on the PSI 90 measures. We intend to continue to report all five HAI measures for the FY 2024 program year with the resulting applicable 12-month period of January 1, 2022 to December 31, 2022 and to report CMS PSI 90 risk adjusted for COVID–19. We will continue to monitor the impacts of these policies and will consider any such issues we identify for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to suppress CY 2021 CDC NHSN HAI measure data from the FY 2024 HAC Reduction Program.

3. Measures for FY 2023 and Subsequent Years

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41474) for more information about how the HAC Reduction Program supports our goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Framework.

A. Current Measures

The HAC Reduction Program has adopted six measures to date. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the use of five CDC NHSN HAI measures: (1) CAUTI; (2) CDI; (3) CLABSI; (4) Colon and Abdominal Hysterectomy SSI; and (5) MRSA bacteremia. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57014), we finalized the use of the CMS PSI 90 measure. These previously finalized measures, with their full measure names, are shown in this table.

HAC Reduction Program Measures for FY 2023 and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
CMS PSI 90	CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716

Technical specifications for the CMS PSI 90 measure can be found on the *QualityNet* website at *https://qualitynet.cms.gov/inpatient/measures/psi/resources*. Technical specifications for the CDC NHSN HAI measures can be found at CDC's NHSN website at *https://www.cdc.gov/nhsn/acute-care-hospital/index.html*. Both websites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In this final rule, we did not add or remove any measures. However, we discuss our proposal to suppress all of the measures for the FY 2023 program year, as discussed in section V.J.2.b.(2) of the preamble of this final rule, and our proposal to suppress CY 2021 CDC NHSN HAI data from the FY 2024 program year, as discussed in section V.J.2.b.(3). Of the preamble of this final rule.

b. Measure Removal Factors Policy

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42404 through 42406) for information about our measure removal and retention factors for the HAC Reduction Program. In this final rule, we did make any measure removal and retention factor policy changes.

c. Technical Measure Specification Updates to the CMS PSI 90 Measure

(1) Technical Measure Specification Update to the Minimum Volume Threshold for the CMS PSI 90 Measure Beginning With the FY 2023 Program Year

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100 through 50101), we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the HAC Reduction Program. We stated our belief that this policy adequately balances our need to incorporate updates to HAC Reduction Program measures in the most expeditious manner possible while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted.

Currently, the minimum volume threshold for the CMS PSI 90 measure requires hospitals to have three or more eligible discharges for at least one component indicator in order to receive a CMS PSI 90 measure score for the HAC Reduction Program (81 FR 57012). Although the CMS PSI 90 measure surpasses the accepted reliability standard, based on an Intracluster Correlation Coefficient (ICC) for hospital-level reporting of at least 0.60 (in a standard 24-month performance period, the CMS PSI 90 measure demonstrated median reliability of 0.74), a small subset of hospitals have a reliability close to zero for their CMS PSI 90 composite score due to the current minimum volume threshold for the measure.

To address this subset of hospitals with a CMS PSI 90 composite score with reliability close to zero, we are instituting a stricter minimum volume threshold for the measure, which would prevent those small hospitals from receiving a CMS PSI 90 composite score. Consistent with the current minimum volume threshold policy, hospitals that do not meet the threshold criteria would not receive a measure result or, subsequently, a measure score (that is., a Winsorized z-score) for the CMS PSI 90 measure and it would not factor into the calculation of their Total HAC Score. Accordingly, in this final rule, we are announcing an increased minimum volume threshold for the CMS PSI 90 measure, under which hospitals would be required to meet both of the following criteria in order to receive a CMS PSI 90 composite score:

- One or more component PSI measure with at least 25 eligible discharges; and
- Seven or more component PSI measures with at least three eligible discharges.

We note that this change to the CMS PSI 90 minimum volume threshold criteria will be applied to both the version of the measure used in HAC Reduction Program scoring calculations as well as the version of the measure displayed on the main pages of the Care Compare tool hosted by the U.S. Department of Health and Human Services, currently available at *https://www.medicare.gov/care-compare*, via updates to the next version of the CMS PSI 90 software. Additional information regarding the technical specifications for the CMS PSI 90 measure can be found on the *QualityNet* website at *https://qualitynet.cms.gov/inpatient/measures/psi/resources*.

An analysis of the impact of this threshold change on HAC Reduction Program results indicates that it would impact the scoring of a small number of low-volume hospitals. As a result of this threshold change, approximately five percent of hospitals would no longer receive a CMS PSI 90 composite score (and, subsequently, a CMS PSI 90 measure score) and approximately half of those hospitals, or 2.5 percent of all hospitals, would no longer receive a Total HAC Score. Accordingly, there will be a decrease in the number of hospitals in the worst-performing quartile. We anticipate that the majority of the hospitals no longer receiving a Total HAC Score will be small hospitals with fewer than 100 beds. Rural

hospitals, which tend to have lower capacity, are also more impacted by the change than urban hospitals. The threshold change only impacts a small number of hospitals in the HAC Reduction Program while improving overall measure reliability.

While we did not solicit comments on this technical measure specification update, we received some comments, which are summarized in this final rule.

Comment: Several commenters supported the technical measure specification update to the minimum volume threshold for CMS PSI 90 beginning with the FY 2023 HAC Reduction Program. A commenter expressed its belief that the update will minimize the unintended consequence of penalizing smaller or low volume hospitals based on scores that that may not demonstrate sufficient reliability.

Response: We thank commenters for their support of the technical measure specification update to increase the minimum volume threshold for CMS PSI 90 beginning with the FY 2023 program year.

Comment: A commenter expressed concern that the updated minimum volume threshold might omit many hospitals from being rated on CMS PSI 90 and would remove these hospitals from accountability.

Response: We appreciate commenter's position, however, as discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28451) the impact analysis of the threshold change indicated that it would impact the scoring of a small number of low-volume hospitals who have a CMS PSI 90 measure reliability close to zero. Approximately just five percent of hospitals included in the HAC Reduction Program would no longer receive a CMS PSI 90 composite score (and, subsequently, a CMS PSI 90 measure score) and approximately just 2.5 percent of all hospitals would no longer receive a Total HAC Score. It should be noted CMS PSI 90 is unreliable for these very low-volume hospitals, as their computed scores from prior program years are tightly clustered around one (that is, the mean value for all hospitals).

Comment: A commenter suggested that we obtain all-payer claims to drive up the denominators, increase reliability, and reduce the number of hospitals who do not qualify for a score. Another commenter recommended that we examine the ICC at minimum threshold rather than at the median and set the minimum volume at a number that will produce an ICC of 0.6 or higher.

Response: We appreciate commenters' recommendations for additional refinements to the technical measure specification update to the minimum volume threshold for CMS PSI 90 beginning with the FY 2023 program year. We will consider the feedback we received for future rulemaking.

Comment: A commenter recommended that since the update to the minimum volume threshold would yield approximately 5 percent of hospitals no longer receiving a CMS PSI 90 score and half of those hospitals would no longer receive a Total HAC Score, CMS should reduce the number of hospitals penalized by a similar factor. The commenter also recommended given these changes to the measure specifications, CMS PSI 90 should be suppressed for the FY 2024 program year to allow time to evaluate the impacts of these specification updates.

Response: We appreciate the suggestion to reduce the number of hospitals penalized for the FY 2024 HAC Reduction Program. We note that the HAC Reduction Program is statutorily required to penalize the worst-performing quartile (that is, the worst-performing 25 percent) of hospitals based on their Total HAC Score in a given program year. Hospitals that do not receive a Total HAC Score are not included in the distribution of hospitals used to determine the 75th percentile. Therefore, a decrease in the number of hospitals receiving a Total HAC Score will also lead to a decrease in the number of hospitals in the worst-performing quartile. We note that we did acknowledge this impact in the FY 2023 IPPS/LTCH proposed rule where we stated that this increase to the minimum volume threshold for CMS PSI 90 would likely yield a reduction in the number of hospitals in the worst-performing quartile for the HAC Reduction Program (87 FR 28451).

We thank the commenter for their suggestion to suppress CMS PSI 90 for the FY 2024 program year. Impact analyses have shown that this update to CMS PSI 90 measure specifications improves overall measure reliability, which in turn improves comparison between hospitals' CMS PSI 90 scores for HAC Reduction Program scoring purposes. Because this measure specification update improves the overall scoring process, we will not suppress CMS PSI 90 for the FY 2024 program year.

(2) Technical Measure Specification Update to Risk-Adjust for COVID–19 Diagnoses in the CMS PSI 90 Measure Beginning With the FY 2024 HAC Reduction Program Year

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45305) for previous analysis on the impact of the COVID–19 PHE on the CMS PSI 90 measure. Our analysis found that the decrease in volume continued in CY 2021 across all component PSI measures, especially those related to surgical procedures for which the denominator volume was 8 percent to 45 percent lower in the first two quarters of CY 2021 than in the corresponding quarters of CY 2019. Our analysis also found that unadjusted rates continued to be high in CY 2021 for patients with a COVID–19 diagnosis compared to patients without a COVID–19 diagnosis, across most of the 10 component measures in CMS PSI 90. However, PSI 90 component rates among patients without COVID–19 were virtually unchanged through the COVID–19 PHE. CMS has found that adjusting for COVID–19 at the patient level entirely removes the incremental risk associated with this diagnosis. After risk-adjustment for COVID–19, PSI component rates appear consistently flat across the first two quarters of 2021.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100 through 50101), we finalized a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program. To address the impact of the COVID–19 PHE on the CMS PSI 90 measure, we are announcing a technical update to the CMS PSI 90 software to include COVID–19 diagnosis as a risk-adjustment parameter for the FY 2024 program year and subsequent years.

While we did not solicit comments on this technical measure specification update, we received some comments, which are summarized in this final rule.

Comment: Many commenters supported the technical measure specification update to risk-adjust for COVID–19 diagnosis in CMS PSI 90 beginning with the FY 2024 program year. Several commenters believed that the update will help address the lingering impacts of the COVID–19 PHE.

Response: We thank commenters for their support of the technical measure specification update to risk-adjust for COVID–19 diagnosis present on admission in CMS PSI 90 beginning with the FY 2024 program year.

Comment: A commenter recommended that CMS continue to monitor whether the PHE would necessitate additional measure changes.

Another commenter recommended that CMS review model performance before reinstituting payment penalties.

Response: We agree with commenters' recommendations regarding continued monitoring of the effects of the COVID–19 PHE. We intend to work with measure developers to refine measure specifications as necessary and feasible for future rulemaking. We appreciate the commenter's feedback regarding reinstituting payment penalties under the HAC Reduction Program. As noted in section V.J.2.b.(2), we understand commenters' concerns regarding the impact of the COVID–19 PHE and will ensure that we monitor and evaluate the data to determine if further suppression is warranted in the future. Though, we note that our goal is to continue resuming the use of measure data for the purposes of scoring and payment adjustment beginning with the FY 2024 HACRP Program. Any proposal to suppress payment penalties for additional program years would be made through future notice-and-comment rulemaking.

Comment: A commenter does not support the technical measure specification update to risk-adjust for COVID–19 diagnosis in CMS PSI 90 beginning with the FY 2024 program year and instead recommended that patients diagnosed with COVID–19 be included in measurement of preventable harms.

Response: We appreciate the commenter's concern, however, as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45305) where we conducted an analysis on the impacts of the COVID–19 PHE on CMS PSI 90, we found that unadjusted rates continued to be high in CY 2021 for patients with a COVID–19 diagnosis compared to patients without a COVID–19 diagnosis, across most of the 10 component measures in CMS PSI 90. In order to address the impact of the COVID–19 PHE on CMS PSI 90, we are implementing the technical measure specification update to risk adjusts for the COVID–19 to mitigate the impacts on measure results and ensure that hospitals are not unfairly scored or penalized through payment due to the COVID–19 PHE.

Comment: A few commenters recommended that CMS release additional details on the CMS PSI 90 risk-adjustment methodology like whether risk-adjustment of COVID–19 diagnosis pertains to a patient's primary or secondary diagnosis. Several commenters recommended that CMS further assess CMS PSI 90 COVID–19 risk adjustment methodology and convene an NQF Technical Expert Panel to evaluate the methodology.

Response: We seek to clarify that risk-adjustment details are released to the public when each version of the software is completed and made available. The first software version that would incorporate COVID–19 risk-adjustment would be version 13. The Risk Adjustment methodology report will be posted on the QualityNet site for CMS PSI 90 Resources at *https://qualitynet.cms.gov/inpatient/measures/psi/resources*. We appreciate commenters' recommendations regarding the technical measure specification update to risk-adjust for COVID–19 diagnosis present on admission in CMS PSI 90 beginning with the FY 2024 program year. We note that the update to the risk adjustment methodology is part of the routine annual process to update CMS PSI 90. As part of that process, the measure developer will submit an annual update to NQF that includes updates to the risk adjustment model.[319]

Comment: A few commenters recommended that CMS implement the COVID–19 risk-adjustment as well as suppress CMS PSI 90 for the first two quarters of CY 2021 of the FY 2024 program year due to the impact of the COVID–19 PHE on hospitals.

Response: We appreciate the commenter's recommendations to risk adjust for COVID–19 and suppress CMS PSI 90 in FY 2024. We will monitor performance in CMS PSI 90 and will consider any issues we identify for future rulemaking.

Comment: A commenter suggested that CMS consider suppression of CMS PSI 90 for the FY 2024 program year based on the evaluation of the technical update impacts as well as impacts from the COVID–19 PHE.

Response: We appreciate the commenter's recommendations to suppress CMS PSI 90 for the FY 2024 program year based on evaluation of the CMS PSI 90 risk adjustment for COVID–19. We will monitor performance in CMS PSI 90 and will consider any issues we identify for future rulemaking.

Comment: A few commenters expressed concern that CMS PSI 90 COVID–19 risk adjustment would reduce the amount of attention and monitoring for patients diagnosed with COVID–19. A commenter recommended that CMS not risk adjust for COVID–19 to address this concern.

Response: We appreciate the commenters concern that CMS PSI 90 COVID–19 risk adjustment would reduce the amount of attention and monitoring for patients diagnosed with COVID–19. However, in the FY 2023 IPPS/LTCH proposed rule, we stated that our analysis of CMS PSI 90 found that unadjusted rates continued to be high in CY 2021 for patients with a COVID–19 diagnosis compared to patients without a COVID–19 diagnosis, across most of the 10 component measures. We note that rates for the component PSI 90 measures among patients without COVID–19 were virtually unchanged through the COVID–19 PHE. We have found that adjusting for COVID–19 at the patient level entirely removes the incremental risk associated with this diagnosis (87FR 28450). In order to address the impact of the COVID–19 PHE on CMS PSI 90, we are implementing this technical measure specification update to ensure that hospitals are not unfairly scored or penalized through payment due to the COVID–19 PHE. Additionally, due to the potentially geographically disparate impacts of the COVID–19 PHE, we believe that risk-adjusting CMS PSI 90 is appropriate to ensure hospitals are not unevenly penalized due to their location.

Comment: A commenter recommended that CMS only confidentially report, without publicly reporting, CMS PSI 90 due to the impacts of COVID–19 for the FY 2024 program year.

Response: We appreciate the commenter's recommendation to not publicly report data for CMS PSI 90 in the FY 2024 program year. To account for the impact of the COVID–19 PHE on CY 2021 data in CMS PSI 90, however, we are updating the measure specifications to risk-adjust for COVID–19 diagnoses present on admission. As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28450), our analysis of the COVID–19 PHE impacts on CY 2021 data found that the decrease in volume continued in CY 2021 across nearly all component PSI measures, especially those related to surgical procedures (for which the denominator volume was 8 percent to 45 percent lower in the first two quarters of CY 2021 than in the corresponding quarters of CY 2019). Our analysis also found that unadjusted rates continued to be high in CY 2021 for patients with a COVID–19 diagnosis compared to patients without a COVID–19 diagnosis. We believe that modifying our proposal to publicly report the CMS PSI 90 measure data for the FY 2023 HAC Reduction Program and continuing to

[319] National Quality Forum. (2022). *Maintenance of NQF-Endorsed Performance Measures.* Available at: *https://www.qualityforum.org/measuring_performance/endorsed_performance_measures_maintenance.aspx.*

publicly report measure data for the FY 2024 HAC Reduction Program will maintain transparency and support consumers in making informed decisions on where to receive care.

Comment: A commenter expressed concern that the modified PSI 90 measure and the partially suppressed HAI measure will not allow for equitable and meaningful Total HAC Scores for FY 2024.

Response: We appreciate the commenters' concern about the meaningfulness of the Total HAC Score for FY 2024 due to the proposed measure suppression and technical measure specification updates. As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28450), we continue to be concerned about measure performance and the national comparability of such performance during the CY 2021 (87 FR 28450). We believe national comparability of hospital performance is very significant, so we are pursuing suppression of the CY 2021 data of the CDC NHSN HAI measures and risk adjustment for COVID–19 diagnosis in CMS PSI 90 to account for COVID–19 diagnosis in the CY 2021.

Comment: A commenter suggested that the COVID–19 risk adjustment may not accurately capture COVID–19 diagnosis due to at-home testing and absence of diagnosis codes.

Response: We acknowledge the commenter's concern about the accuracy of risk adjusting for COVID–19 in CMS PSI 90. Although COVID–19 diagnoses may be under-reported to public health authorities due to at-home testing, this concern does not apply to inpatient hospitals that routinely repeat at-home test results.

d. HAC Reduction Program Requests for Information

(1) Digital CDC NHSN Measures

We refer readers to section IX.E.9.a. of this final rule, for a discussion of the comments received regarding this cross-program request for information on the potential future adoption of two digital NHSN measures, the NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome Measure and the NHSN Hospital-Onset Bacteremia & Fungemia Outcome Measure, into the Hospital IQR Program, PCHQR Program, and the LTCH QRP. In addition, we requested information on the potential inclusion of these digital CDC NHSN measures in the HAC Reduction Program. This request for information supports our goal of moving fully to digital quality measurement in CMS quality reporting and value-based purchasing programs, including the HAC Reduction Program.

(2) Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

We refer readers to section IX.B. of this final rule where we sought input on overarching principles in measuring healthcare quality disparities in hospital quality and value-based purchasing programs.

4. Proposal To Update the CDC NHSN HAI Data Submission Requirements for Newly Opened Hospitals Beginning in the FY 2023 HAC Reduction Program Year

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57013), we finalized CDC NHSN HAI data submission requirements for newly-opened hospitals under the HAC Reduction Program that referred to the date that a hospital filed a notice of participation (NOP) with the Hospital IQR Program. At the time, the HAC Reduction Program obtained measure results that hospitals submitted to the CDC NHSN from the Hospital IQR Program. However, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41545 through 41553), we transferred our collection of the CDC NHSN HAI measures from the Hospital IQR Program to the HAC Reduction Program beginning with CY 2020 data. Given the transition from the Hospital IQR Program, the NOP requirements noted in the FY 2017 IPPS/LTCH PPS final rule do not apply.

We proposed to update the definition of ''newly-opened hospitals'' for the CDC NHSN HAI measures to include hospitals with a Medicare Accept Date within the last 12 months of the performance period.[320] Under the HAC Reduction Program scoring methodology, hospitals that are defined as newly-opened hospitals for the CDC NHSN HAI measures would not receive a measure score for any of the CDC NHSN HAI measures.

The number of hospitals impacted by this change in criteria is small, less than one-quarter percent of hospitals. Hospitals with a Medicare Accept Date between the 12th and the 6th month before the end of the HAI performance period (January 1, 2021 to June 30, 2021 for the FY 2023 program year) do not meet the current criteria for newly-opened hospitals for the CDC NHSN HAI measures, but would meet the updated criteria.[321] In addition, all of these hospitals do not have 12 months of CMS PSI 90 data and because of this already do not receive a measure score for that measure. Therefore, all impacted hospitals would not receive a Total HAC Score for the program year and could not be subject to the one percent payment reduction. As per the measure suppression policy discussed in section V.J.2.b.(2). we proposed to suppress all six measures in the program for the FY 2023 program year, so no hospitals will be impacted by this change for the FY 2023 program year.

An analysis of the number of hospitals not meeting the current definition of ''new hospitals'' that would meet the criteria under this new proposed definition indicate that 0.22 percent of hospitals would have been affected by this definition change in the FY 2021 program year and 0.09 percent in the FY 2020 program year.

We invited public comments on this proposal to update the newly-opened hospital definition for CDC NHSN HAI measures beginning in the FY 2023 program year.

Comment: A commenter supported the proposal to update the CDC NHSN HAI data submission requirements for newly opened hospitals beginning in the FY 2023 HAC Reduction Program and recommended that CMS ensure the proposal does not increase hospital compliance burden.

Response: We thank the commenter for its support and note that the proposal does not affect requirements for data submission, but only affects which hospitals receive a measure score.

After consideration of the public comments we received, we are finalizing our proposal to update the ''newly-opened hospital'' definition for CDC NHSN HAI measures beginning in the FY 2023 program year.

5. HAC Reduction Program Scoring Methodology and Scoring Review and Corrections Period

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41484 through 41489), we adopted the Equal Measure Weights approach to scoring and clarified the Scoring Calculations Review and

[320] Because the CMS PSI 90 measure requires at least 12 months of measure data (81 FR 50712), hospitals that open during the final 12 months of the performance period would also not receive a CMS PSI 90 measure score.

[321] There is a small subset of hospitals with a Medicare Accept Date between the 6th and 9th month before the end of the HAI performance period (April 1, 2021, to June 30, 2021 for the FY 2023 program year) and a Hospital IQR Program Notice of Participation Date during the last quarter of the HAI performance period (before October 1, 2021 or after December 31, 2021 for the FY 2023 program year), that are also currently defined as newly-opened hospitals. These hospitals' newly-opened status would not be impacted by this criteria change.

Correction Period (83 FR 41484) for the HAC Reduction Program. Hospitals must register for a *QualityNet* website's secure portal account in order to access their annual hospital-specific reports. In this final rule we are not making any changes to the Scoring Calculations Review and Correction Period process.

We note that in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to temporarily suppress all measures from the FY 2023 HAC Reduction Program. We proposed to calculate the measure results for the five CDC NHSN HAI measures for the FY 2023 HAC Reduction Program, but to not use those measure results to calculate measure scores (that is, Winsorized z-scores) for any of the measures because of our concerns regarding the comparability of measure results. Additionally, we proposed to not calculate measure results for the CMS PSI 90 measure nor publicly report the measure on the Care Compare tool hosted by Health and Human Services and the Provider Data Catalog. We also proposed that all hospitals would receive a Total HAC Score of zero, and no hospitals would receive a penalty for FY 2023. We intend to resume the previously adopted HAC Reduction Program scoring methodology in FY 2024 (with the proposed suppression of CY 2021 CDC NHSN HAI data as discussed in section V.J.2.b.(3).) and for subsequent years. In section V.J.2.b.(2)., we invited public comment on the proposal to temporarily suppress all measures from the FY 2023 HAC Reduction Program.

6. Validation of HAC Reduction Program Data

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we adopted processes to validate the CDC NHSN HAI measure data used in the HAC Reduction Program, because the Hospital IQR Program finalized its proposals to remove CDC NHSN HAI measures from its program. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42406 through 42410), we provided additional clarification to the validation selection and scoring methodology. We also refer readers to the *QualityNet* website for more information regarding chart-abstracted data validation of measures. In the FY 2020 IPPS/LTCH PPS final rule (85 FR 58862 through 58865), we finalized our policy to align the HAC Reduction Program validation process with that of the Hospital IQR Program. Specifically, we aligned the hospital selection and submission quarters beginning with CY 2021 data for the FY 2024 Hospital IQR and HAC Reduction Programs validation so that we only require one pool of hospitals to submit data for validation. Additionally, we finalized a policy requiring hospitals to submit digital files when submitting medical records for validation of HAC Reduction Program measures, for the FY 2024 program year and subsequent years.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58862 through 58865), we finalized our policy that for the FY 2024 program year and subsequent years, we will use measure data from all of CY 2021 for both the HAC Reduction Program and the Hospital IQR Program, which must be reported using the validation schedule posted on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System.

In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to suppress all measures from the FY 2023 program and CY 2021 CDC NHSN HAI data from the FY 2024 HAC Reduction Program, respectively. As discussed in those sections, hospitals are still required to submit such data and such data will be used for validation purposes. If hospitals do not submit measure data for validation during the FY 2024 program year, then those hospitals will automatically receive the maximum Winsorized z-score for the measure in the FY 2024 program year payment calculation. We therefore are not making any changes to the policies regarding measure validation in this final rule.

7. Clarification of the Removal of the ''No Mapped Locations'' Policy Beginning With the FY 2023 Program Year

Under the HAC Reduction Program, hospitals have historically been able to receive a ''no mapped locations (NML)'' exemption [322] for the CLABSI and CAUTI measures.[323] This exemption has been applied when hospitals do not map an applicable ward (that is, Intensive Care Units (ICUs), surgical, medical, and medical-surgical wards) in the NHSN system, do not submit data for the measures, and do not submit an IPPS Measure Exception Form.[324]

In this final rule we would like to clarify the removal of the No Mapped Locations (NML) policy. The CDC has confirmed that the NML exemption does not indicate that a hospital does not need to report data, and that hospitals requesting to be exempt from reporting for CMS quality programs including the HAC Reduction Program, should submit an IPPS Measure Exception Form on the QualityNet website at *https://qualitynet.cms.gov/files/5e3459aa152a7d001f93d36c?filename=IPPS_MeasureExceptionForm_CY2020.pdf*. Therefore, we want to clarify that beginning in FY 2023 and subsequent years, the NML designation will no longer apply, and hospitals will be required to appropriately submit data to the NHSN or, if hospitals do not have the applicable locations for the CLABSI and CAUTI measures, the hospital must submit an IPPS Measure Exception Form to be exempt from CLABSI and CAUTI reporting for CMS programs. If the hospitals do not submit an IPPS Measure Exception Form and continue to not submit data to the NHSN, these hospitals would receive the maximum measure score (that is., Winsorized z-score) under the HAC Reduction Program for not reporting data. In the FY 2020 IPPS/LTCH PPS final rule, we instructed hospitals that do not have adequate locations for CLABSI or CAUTI reporting to submit the IPPS Measure Exception Form to the HAC Reduction Program beginning on January 1, 2020 (84 FR 42406), and the removal of the NML policy has previously been communicated in the FY 2022 HAC Reduction Program Frequently Asked Questions [325] and the FY 2022 HAC Reduction Program HSR User Guide.[326] Additionally, because NML only applies to a small subset of hospitals, we plan to execute targeted outreach via email to those hospitals that had received the exception in the past two program years notifying them of the removal of the NML policy.

For more details on the NML designation and policy, we refer readers to the FY 2022 Hospital Specific Report (HSR) User Guide located on QualityNet website at *https://qualitynet.cms.gov/files/61152cf0a248cb001efce449?filename=FY_2022_HACRP_HSR_User_Guide.pdf* and the FY 2022 HAC Reduction Program Frequently Asked Questions website at *https://*

[322] Prior to FY 2018, the program used the term No Facilities Waiver for this same situation. Centers for Medicare & Medicaid Services. (2017). HACRP HAI Webinar Slides Final. Available at: *https://www.qualityreportingcenter.com/globalassets/migrated-pdf/vbp-iqr-hacrp_hai_webinar_slides_vfinal508.pdf*.

[323] Centers for Medicare and Medicaid Services. (2021). FY 2022 HACRP HSR User Guide. Available at: *https://qualitynet.cms.gov/files/61152cf0a248cb001efce449?filename=FY_2022_HACRP_HSR_User_Guide.pdf*.

[324] The valid OMB control number for the IPPS Measure Exception Form is 0938–1022.

[325] Centers for Medicare and Medicaid Services. (2021). FY 2022 HACRP FAQs. Available at: *https://qualitynet.cms.gov/files/61152d1252b92f00229e9717?filename=FY_2022_HACRP_FAQ.pdf*.

[326] Centers for Medicare and Medicaid Services. (2021). FY 2022 HACRP HSR User Guide. Available at: *https://qualitynet.cms.gov/files/61152cf0a248cb001efce449?filename=FY_2022_HACRP_HSR_User_Guide.pdf*.

qualitynet.cms.gov/files/61152d1252b92f00229e9717?filename=FY_2022_HACRP_FAQ.pdf.

While we did not solicit comments on this clarification, we received some comments, which are summarized later in this section.

Comment: A commenter supported the clarification of the removal of the No Mapped Locations policy and recommended that targeted outreach to affected hospitals be expanded beyond email.

Response: We thank the commenter for its support for the removal of the No Mapped Locations policy and we will take into consideration the recommendation to expand targeted outreach to additional modalities beyond email correspondence.

Comment: A commenter did not support the requirement for hospitals to submit an IPPS Measure Exception Form to be exempt from CLABSI and CAUTI reporting for our programs when they have no applicable locations.

Response: We appreciate the commenter's concern; however, we believe that this requirement is necessary to maintain alignment with the CDC's recommendations as well as ensure clear and transparent hospital reporting.

8. Extraordinary Circumstances Exception (ECE) Policy for the HAC Reduction Program

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38276 through 38277) for discussion of our Extraordinary Circumstances Exception (ECE) policy. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581), we adopted an ECE policy for the HAC Reduction Program, which recognized that there may be periods of time during which a hospital is not able to submit data in an accurate or timely fashion due to an extraordinary circumstance beyond its control. When adopting this policy, we noted that we considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's measure results or Total HAC Score for the applicable performance period. By minimizing the data excluded from the program, the policy enabled affected hospitals to continue to participate in the HAC Reduction Program for a given fiscal year if they otherwise continued to meet applicable measure minimum threshold requirements. We expressed the belief that this approach would help alleviate the burden for a hospital that might be adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the HAC Reduction Program. In developing this policy, we considered a policy and process similar to that for the Hospital IQR Program, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), modified by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) (designation of a non-CEO hospital contact), and further modified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) (amended § 412.40(c)(2)) to refer to ''extension or exemption'' instead of the former ''extension or waiver''). We also considered how best to align an extraordinary circumstance exception policy for the HAC Reduction Program with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs, such as the Hospital Value-Based Purchasing (VBP) Program, to the extent feasible. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38276 through 38277), we modified the requirements for the HAC Reduction Program ECE policy to further align with the processes used by other quality reporting and value-based purchasing programs for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control.

In response to the COVID–19 PHE, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based purchasing programs. On September 2, 2020, we published the interim final rule with comment period (IFC), ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820). The IFC updated the ECE we granted in response to the COVID–19 PHE, for the HAC Reduction Program and several other quality reporting programs (85 FR 54827 through 54838). In the IFC, we updated the previously announced application of our ECE policy for the HAC Reduction Program (85 FR 54830 through 54832) to the COVID–19 PHE to exclude any CDC NHSN HAI data submitted regarding care provided during the first and second quarters of CY 2020 from our calculation of performance for FY 2022 and FY 2023.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45308 through 45310), we clarified our ECE policy to highlight that an ECE granted under the HAC Reduction Program may allow an exception from quality data reporting requirements and may grant a request to exclude any data submitted (whether submitted for claims purposes or to the CDC NHSN) from the calculation of a hospital's measure results or Total HAC Score for the applicable period, depending on the exact circumstances under which the request was made.

Finally, in the FY 2022 IPPS/LTCH PPS final rule we clarified that, although an approved ECE for the HAC Reduction Program would exclude excepted data and grant an exception with respect to data reporting requirements for the period during which performance or ability to submit data was impacted or both, a hospital would still be evaluated for the remainder of the applicable period during which performance and ability to submit data was not impacted (to the extent that enough data are available to ensure that the calculation is statistically sound) or both. We clarified that an approved ECE for the HAC Reduction Program does not exempt hospitals from payment reductions under the HAC Reduction Program (86 FR 45309 through 45310).

We have not made any changes to our previously finalized ECE Policy in this final rule.

K. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). The demonstration has been extended three times since the original 5-year period mandated by the MMA, each time for an additional 5 years. These extensions were authorized by sections 3123 and 10313 of the Affordable Care Act (ACA) (Pub. L. 111–148), section 15003 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) enacted in 2016, and most recently, by section 128 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260). In this final rule, we follow upon the FY 2023 IPPS proposed rule, and summarize the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality.

We are also stating the finalized amount to be applied to the national IPPS payment rates to account for the costs of the demonstration in FY 2023, and, in addition, the reconciled amount of demonstration costs for FY 2017, the

most recent year for which finalized cost reports have become available.

2. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

3. Policies for Implementing the 5-Year Extension Period Authorized by Public Law 116–260

Our policy for implementing the 5-year extension period authorized by Public Law 116–260 (the Consolidated Appropriations Act of 2021) follows upon that for the previous extensions, under the ACA (Pub. L. 111–148) and the Cures Act (Pub. L.114–255).

Section 410A of Public Law 108–173 (MMA) initially required a 5-year period of performance. Subsequently, sections 3123 and 10313 of Pub. L. 111–148 (ACA) required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Public Law 111–148 required the Secretary to provide for the continued participation of rural community hospitals in the demonstration program during this 5-year extension period, in the case of a rural community hospital participating in the demonstration program as of the last day of the initial 5-year period, unless the hospital made an election to discontinue participation. In addition, Public Law 111–148 limited the number of hospitals participating to no more than 30.

Section 15003 of the Cures Act required the Secretary to conduct the demonstration for a 10-year extension period (in place of the 5-year extension period required by Public Law 111–148 (ACA)). Specifically, section 15003 of Public Law 114–255 (Cures Act) amended section 410A(g)(4) of Public Law 108–173 (MMA) to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary would provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital made an election, in such form and manner as the Secretary may specify, to discontinue participation. In addition, section 15003 of Public Law 114–255 added subsection (g)(5) to section 410A of Public Law 108–173 to require that, during the second 5 years of the 10-year extension period, the Secretary would apply the provisions of section 410A(g)(4) of Public Law 108–173 to rural community hospitals not described in subsection (g)(4) but that were participating in the demonstration as of December 30, 2014, in a similar manner as such provisions apply to hospitals described in subsection (g)(4).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38280), we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those previously participating hospitals choosing to participate in the second 5-year extension period. According to our finalized policy, each previously participating hospital began the second 5 years of the 10-year extension period and payment for services provided under the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Pub. L. 114–255) on the date immediately after the period of performance ended under the first 5-year extension period.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by Public Law 111–148 (ACA) elected to continue in the 5-year extension period authorized by Public Law 114–255 (Cures Act). Therefore, for these hospitals, this third 5-year period of participation started on dates ranging from May 1, 2015 through January 1, 2017, depending on when they had initially started.

On November 20, 2017, we announced that 13 additional hospitals were selected to participate in the demonstration in addition to these 17 hospitals continuing participation from the first 5-year extension period. (These two groups are referred to as ''newly participating'' and ''previously participating'' hospitals, respectively.) We announced that each of these newly participating hospitals would begin its 5-year period of participation effective with the start of the first cost-reporting period on or after October 1, 2017. One of the newly participating hospitals withdrew from the demonstration program prior to beginning participation in the demonstration on July 1, 2018. In addition, one of the previously participating hospitals closed effective January 2019, and another withdrew effective October 1, 2019. Therefore, 27 hospitals were participating in the demonstration as of October 1, 2019—15 previously participating and 12 newly participating.

Each hospital has had its own end date applicable to this third five-year period for the demonstration. For four of the previously participating hospitals, this end date fell within FY 2020, while for 11 of the previously participating hospitals, the end date fell within CY 2021. (One of the hospitals within this group chose in February of 2020 to withdraw effective September of the previous year). The newly participating hospitals were all scheduled to end their participation either at the end of FY 2022 or during FY 2023.

Section 128 of the Consolidated Appropriations Act of 2021 (CAA), Public Law 116–260 requires a 15-year extension period, to begin on the date immediately following the last day of the initial 5-year period, instead of the 10-year extension period mandated by the Public Law 114–255 (Cures Act). In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019. Therefore, in the FY 2022 IPPS final rule (86 FR 45314), we stated our interpretation of the statute as providing for an additional 5-year period under the reasonable cost-based reimbursement methodology for the demonstration for the 26 hospitals whose effective participation extended back to December 30, 2019.

Given that four hospitals ended the 5-year period authorized by the Cures Act during FY 2020, we finalized the policy from previous extensions, that is, to apply the cost-based reimbursement methodology to the date following the last day of this previous period for each hospital that elects to continue participation. Likewise, each of the 22 hospitals with a scheduled end date during 2021, 2022, or 2023 is eligible for an additional 5-year period starting from the day after the specified end date. Accordingly, the period of participation for the last hospital in the demonstration under this most recent

legislative authorization would extend until June 30, 2028.

4. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount that the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. We note that the payment methodology for this demonstration, that is, cost-based payments to participating small rural hospitals, makes it unlikely that increased Medicare outlays will produce an offsetting reduction to Medicare expenditures elsewhere. Therefore, in the 12 IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (A different methodology was applied for FY 2017.) As we discussed in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the statutory language of the budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

b. General Budget Neutrality Methodology

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year.

We note that we have calculated this difference for FYs 2005 through 2016 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

c. Budget Neutrality Methodology for the Extension Period Authorized by Public Law 116–260

For the newly enacted extension period, under the CAA, we continue upon the general budget neutrality methodology used in previous years, and to specifically follow upon the determinations for the previous extension period, under the Cures Act.

(1) Budget Neutrality Methodology for Previous Extension Period Under the Cures Act

We finalized our budget neutrality methodology for periods of participation under this previous 5-year extension period in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38285 through 38287). Similar to previous years, we stated in this rule, as well as in the FY 2019 and FY 2020 IPPS/LTCH PPS proposed and final rules (83 FR 20444 and 41503, and 84 FR 19452 and 42421, respectively) that we would incorporate an estimate of the costs of the demonstration, generally determined from historical, ''as submitted'' cost reports for the participating hospitals, and appropriate update factors, into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In addition, we stated that we would continue to apply our general policy from previous years of including, as a second component to the budget neutrality offset amount, the amount by which the actual costs of the demonstration for an earlier, given year (as determined from finalized cost reports, when available) differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year.

In these proposed and final rules, we described several distinct components to the budget neutrality offset amount for the specific fiscal years of the extension period authorized by Public Law 114–255 (Cures Act).

We included a component to our overall methodology similar to previous years, according to which an estimate of the costs of the demonstration for both previously and newly participating hospitals for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In the FY 2019 IPPS final rule (83 FR 41506), we included such an estimate of the costs of the demonstration for each of FYs 2018 and 2019 into the budget neutrality offset amount for FY 2019. In the FY 2020 IPPS final rule (84 FR 42421), we included an estimate of the costs of the demonstration for FY 2020 for 28 hospitals. In the FY 2021 IPPS final rule (85 FR 58873), we included an estimate of the costs of the demonstration for FY 2021 for the 22 hospitals for which the cost-based reimbursement methodology was to apply for all or part of FY 2021. In the FY 2022 IPPS final rule (86 FR 45316), we included an estimate of the costs of the demonstration for FY 2022 for the 26 hospitals expected to participate in that fiscal year.

Similar to previous years, we continued to implement the policy of determining the difference between the actual costs of the demonstration as determined from finalized cost reports for a given fiscal year and the estimated costs indicated in the corresponding year's final rule, and including that difference as a positive or negative adjustment in the upcoming year's final rule. (For each previously participating hospital that decided to participate in the 5-year extension period under the Cures Act, the cost-based payment methodology under the demonstration

began on the date immediately following the end date of its period of performance for the still previous extension period (under the ACA). In addition, for previously participating hospitals that converted to CAH status during the time period of the second 5-year extension period, the demonstration payment methodology was applied to the date following the end date of its period of performance for the first extension period to the date of conversion). In the FY 2020 final rule, we included the difference between the amount determined for the cost of the demonstration in each of FYs 2014 and 2015 and the estimated amount included in the budget neutrality offset in the final rule for each of these respective fiscal years. In the FY 2022 final rule, we included the difference between the amount determined for the cost of the demonstration in FY 2016 and the estimated amount included in the budget neutrality offset in the final rule for that fiscal year.

(2) Methodology for Estimating Demonstration Costs for FY 2022

We are using a methodology similar to previous years, according to which an estimate of the costs of the demonstration for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year, that is, FY 2023. We are conducting this estimate for FY 2023 based on the 26 hospitals that are continuing participation in demonstration for the fiscal year. The methodology for calculating this amount for FY 2023 proceeds according to the following steps:

Step 1: For each of these 26 hospitals, we identify the reasonable cost amount calculated under the reasonable cost-based methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. For each of these hospitals, the ''as submitted'' cost report is that with cost report period end date in CY 2020. We sum these hospital-specific amounts to arrive at a total general amount representing the costs for covered inpatient hospital services, including swing beds, across the total 26 hospitals eligible to participate during FY 2023.

Then, we multiply this amount by the FYs 2021, 2022 and 2023 IPPS market basket percentage increases, which are calculated by the CMS Office of the Actuary. (Unlike in the proposed rule, where used the proposed market basket percentage increase for FY 2023, for this final rule, we use the final market basket percentage increase, which can be found at section X.XX of the preamble to this final rule). The result for the 26 hospitals is the general estimated reasonable cost amount for covered inpatient hospital services for FY 2022.

Consistent with our methods in previous years for formulating this estimate, we are applying the IPPS market basket percentage increases for FYs 2021 through 2023 to the applicable estimated reasonable cost amount (previously described) in order to model the estimated FY 2023 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise be paid in FY 2023 under applicable Medicare payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. We sum these hospital-specific amounts, and, in turn, multiply this sum by the FYs 2021, 2022 and 2023 IPPS applicable percentage increases. (For FY 2023, we are using the final applicable percentage increase for FY 2023, per section X.XX of the preamble of this final rule). This methodology differs from Step 1, in which we apply the market basket percentage increases to the hospitals' applicable estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Step 3: We subtract the amount derived in Step 2 from the amount derived in Step 1. According to our methodology, the resulting amount indicates the total difference for the 26 hospitals (for covered inpatient hospital services, including swing beds), which will be the general estimated amount of the costs of the demonstration for FY 2023.

For this final rule, the resulting amount is $72,449,896, which we are incorporating into the budget neutrality offset adjustment for FY 2023. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical update factors for cost and payment. In the proposed rule, we stated that if updated data become available prior to the final rule, we would use them as appropriate to estimate the costs for the demonstration program for FY 2023 in accordance with our methodology for determining the budget neutrality estimate. Accordingly, we are using the specific market basket and applicable percentage increases identified in this final rule in estimating the budget neutrality offset amount for FY 2023. In future years, we will also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration.

(3) Reconciling Actual and Estimated Costs of the Demonstration for Previous Years

As described earlier, we have calculated the difference for FYs 2005 through 2016 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years. As we stated in the FY 2023 proposed rule, all of the finalized cost reports are available for the 17 hospitals that completed cost report periods beginning in FY 2017 under the demonstration payment methodology; these cost reports show the actual costs of the demonstration for this fiscal year to be $35,989,928. This amount is unchanged from the proposed rule.

We note that the FY 2017 IPPS final rule included no budget neutrality offset amount for that fiscal year. The final rule for FY 2017 preceded the re-authorization of the demonstration under the Cures Act. Anticipating that the demonstration would end in 2016, we projected no demonstration cost estimate for the upcoming fiscal year, FY 2017, while we stated our plan to continue to reconcile actual costs when all finalized cost reports for previous fiscal years under the demonstration became available (81 FR 57037).

Thus, keeping with past practice, as described in the proposed rule, we are including the actual costs of the demonstration as determined from finalized cost reports for FY 2017 within the budget neutrality offset amount for this upcoming fiscal year.

(4) Total Proposed Budget Neutrality Offset Amount for FY 2023

Therefore, for this FY 2023 IPPS/LTCH PPS final rule, the budget neutrality offset amount for FY 2023 is based on the sum of two amounts:

(a) the amount determined under section X.4.c.(2) of the preamble of this final rule, representing the difference applicable to FY 2023 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 26 hospitals participating in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $72,449,896.

(b) the amount determined under section X.4.c.(3) of the preamble of this final rule, indicating the amount by which the actual costs of the demonstration in FY 2017 as shown by finalized cost reports from that fiscal year exceed the estimated amount identified in the FY 2017. Since no budget neutrality offset was conducted in FY 2017, the amount of this difference is the actual cost amount for FY 2017 ($35,989,928)

Thus, we are subtracting the sum of these amounts ($108,439,824) from the national IPPS rates for FY 2023.

Comment: The parent company for two of the participating hospitals expressed support for the continuation of the Rural Community Hospital Demonstration program, but noted that it does not offer long-term financial stability needed to maintain health care access in rural areas. The commenter requests that the demonstration be made a permanent program, and, in addition, requests several technical modifications to how payment is conducted and costs are audited under the demonstration:

Response: We appreciate the first comment. We have conducted the demonstration program in accordance with Congressional mandates. Title XVIII does not extend authority to make the demonstration a permanent program. With regard to the further comments, we will work with the entire group of hospitals participating in the demonstration in examining the relevant policy and administrative issues.

VI. Changes to the IPPS for Capital Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Annual Update for FY 2023

The annual update to the national capital Federal rate, as provided for in 42 CFR 412.308(c), for FY 2023 is discussed in section III. of the Addendum to this FY 2023 IPPS/LTCH PPS final rule.

In section II.C. of the preamble of this FY 2023 IPPS/LTCH PPS final rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the adjustment to the standardized amount under section 1886(d) of the Act that we are making for FY 2023, in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA. Because these provisions require us to make an adjustment only to the operating IPPS standardized amount, we are not making a similar adjustment to the national capital Federal rate (or to the hospital-specific rates).

VII. Changes for Hospitals Excluded From the IPPS

A. Rate-of-Increase in Payments to Excluded Hospitals for FY 2023

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs. Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating basket to a 2014 base year, effective for FY 2018 and subsequent fiscal years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years.

As discussed in section IV. of the preamble of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45207), we rebased and revised the IPPS operating basket to a 2018 base year. Therefore, we used the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2022 and subsequent fiscal years.

For the FY 2023 IPPS/LTCH PPS proposed rule, based on IGI's 2021 fourth quarter forecast, we estimated that the 2018-based IPPS operating market basket update for FY 2023 would be 3.1 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed that if more recent data became available for the FY 2023 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2023. We did receive updated data. Therefore, for this FY 2023 IPPS/LTCH PPS final rule, based on IGI's 2022 second quarter forecast, we estimate that the 2018-based IPPS operating market basket update for FY 2023 is 4.1 percent. Based on this estimate, the FY 2023 rate-of-increase percentage that will be applied to the FY 2022 target amounts in order to calculate the FY 2023 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa will be 4.1 percent, in accordance with the applicable regulations at 42 CFR 413.40.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). (For additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).)

Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2023, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2023 the proposed update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for FY 2023, which would be equal to the percentage increase in the hospital market basket, which is estimated to be the percentage increase in the 2018-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2023 was 3.1 percent, which was

based on IGI's fourth quarter 2021 forecast. Furthermore, we proposed that if more recent data became available for the FY 2023 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2023. For this FY 2023 IPPS/LTCH PPS final rule, based on IGI's second quarter 2022 forecast, we estimate that the 2018-based IPPS operating market basket update for FY 2023 is 4.1 percent.

We received no comments on this proposal and therefore are finalizing this provision without modification. Incorporating more recent data available for this final rule, as we proposed, we are adopting a 4.1 percent update for FY 2023.

B. Report on Adjustment (Exception) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, adjusting, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for the fiscal year in accordance with § 413.24(f)(2) of the regulations. The MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the MAC receives the hospital's request in accordance with applicable regulations, the MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the request applications are incomplete and additional information must be requested in order to have a completed request application. However, in an attempt to provide interested parties with data on the most recent adjustment payments for which we have data, we are publishing data on adjustment payments that were processed by the MAC or CMS during FY 2021.

The table that follows includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2021. As indicated previously, the adjustments made during FY 2021 only pertain to cost reporting periods ending in years prior to FY 2020. Total adjustment payments made to IPPS-excluded hospitals during FY 2021 are $25,950,692. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Cancer Hospitals	7	$48,831,338	$24,623,016
Children's Hospitals	2	$1,774,147	$1,015,213
RNHCIs	4	$330,405	$312,463
Total	**13**	**$51,935,890**	**$25,950,692**

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project Demonstration

a. Introduction

The Frontier Community Health Integration Project Demonstration was originally authorized by section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). The demonstration has been extended by section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) for an additional 5 years. In this final rule, we are summarizing the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality for the demonstration extension period.

b. Background and Overview

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), section 123 of the Medicare Improvements for Patients and Providers Act of 2008, as amended by section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and commonly known as the Frontier Community Health Integration Project (FCHIP) Demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is a Medicare Rural Hospital Flexibility Program (MRHFP) grantee under section 1820(g) of the Act (that is, a CAH); and is located in a state in which at least 65 percent of the counties in the state are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. In addition, section 123(g)(1)(B) of Pub. L. 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275

stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration. CMS selected CAHs to participate in four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Section 123 of Public Law 110–275 initially required a 3-year period of performance. The FCHIP Demonstration began on August 1, 2016, and concluded on July 31, 2019 (referred to in this section of the final rule as the ''initial period''). Subsequently, section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) extended the demonstration by 5 years (referred to in this section of the final rule as the ''extension period''). The Secretary is required to conduct the demonstration for an additional 5-year period. CAHs participating in the demonstration project during the extension period shall begin such participation in the cost reporting year that begins on or after January 1, 2022.

As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), 10 CAHs were selected for participation in the demonstration initial period. The selected CAHs were located in three states—Montana, Nevada, and North Dakota—and participated in three of the four interventions identified in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 through 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58896) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328). Each CAH was allowed to participate in more than one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention.

In the FY 2022 IPPS/LTCH PPS final rule, CMS concluded that the initial period of the FCHIP Demonstration (covering the performance period of August 1, 2016, to July 31, 2019) had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration.

Section 129 of Public Law 116–260, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, six have elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing three of the four interventions. The eligible CAH participants elected to change the number of interventions and payment waivers they would participate in during the extension period. CMS accepted and approved the CAHs intervention and payment waiver updates. For the extension period, five CAHs are participants in the telehealth intervention, four CAHs are participants in the skilled nursing facility/nursing facility bed intervention, and three CAHs are participants in the ambulance services intervention. As with the initial period, each CAH was allowed to participate in more than one of the interventions during the extension period. None of the selected CAHs are participants in the home health intervention, which was the fourth intervention.

c. Intervention Payment and Payment Waivers

As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS waived certain Medicare rules for CAHs participating in the demonstration initial period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility (SNF/NF) beds expansion. The payments and payment waiver provisions only apply if the CAH is a participant in the associated intervention. Given updates to Medicare payment rules and regulations, CMS has modified and/or updated the Intervention Payment and Payment Waivers for the extension period. The FCHIP payment waivers for the demonstration extension period consist of the following:

(1) Telehealth Services Intervention Payments

CMS waives section 1834(m)(2)(B) of the Act, which specifies the facility fee to the originating site. CMS modifies the facility fee payment specified under section 1834(m)(2)(B) of the Act to make reasonable cost-based reimbursement to the participating CAH where the participating CAH serves as the originating site for a telehealth service furnished to an eligible telehealth individual, as defined in section 1834(m)(4)(B) of the Act. CMS would reimburse the participating CAH serving as the originating site at 101 percent of its reasonable costs for overhead, salaries and fringe benefits associated with telehealth services at the participating CAH. CMS would not fund or provide reimbursement to the participating CAH for the purchase of new telehealth equipment.

CMS waives section 1834(m)(2)(A) of the Act, which specifies the payment made for a telehealth service furnished by the distant site practitioner. CMS modifies the distant site payment specified under section 1834(m)(2)(A) of the Act to make reasonable cost-based reimbursement to the participating CAH for telehealth services furnished by a physician or practitioner located at distant site that is a participating CAH that is billing for the physician or practitioner professional services. Whether the participating CAH has or has not elected Optional Payment Method II for outpatient services, CMS would pay the participating CAH 101 percent of reasonable costs for telehealth services when a physician or practitioner has reassigned their billing rights to the participating CAH and furnishes telehealth services from the participating CAH as a distant site practitioner. This means that participating CAHs that are billing under the Standard Method on behalf of employees who are physicians or practitioners (as defined in section 1834(m)(4)(D) and (E) of the Act, respectively) would be eligible to bill for distant site telehealth services furnished by these physicians and practitioners. Additionally, CAHs billing under the Optional Method would be reimbursed based on 101 percent of reasonable costs, rather than paid based on the Medicare physician fee schedule, for the distant site telehealth services furnished by physicians and practitioners who have reassigned their billing rights to the CAH. For distant site telehealth services furnished by physicians or practitioners who have not reassigned billing rights to a participating CAH, payment to the distant site physician or practitioner would continue to be made as usual under the Medicare physician fee schedule. Currently these services are eligible to be furnished and paid in this way due to a waiver issued during the PHE. Except as described herein, CMS does not waive any other provisions of section 1834(m) of the Act

for purposes of the telehealth services intervention payments, including the scope of Medicare telehealth services as established under section 1834(m)(4)(F) of the Act. We received no comments on this proposal and therefore are finalizing this provision without modification.

(2) Ambulance Services Intervention Payments

CMS waives 42 CFR 413.70(b)(5)(D) and section 1834(l)(8) of the Act, which provides that payment for ambulance services furnished by a CAH, or an entity owned and operated by a CAH, is 101 percent of the reasonable costs of the CAH or the entity in furnishing the ambulance services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. The participating CAH would be paid 101 percent of reasonable costs for its ambulance services regardless of whether there is any provider or supplier of ambulance services located within a 35-mile drive of the participating CAH or participating CAH-owned and operated entity. CMS would not make cost-based payment to the participating CAH for any new capital (for example, vehicles) associated with ambulance services. This waiver does not modify any other Medicare rules regarding or affecting the provision of ambulance services. We received no comments on this proposal and therefore are finalizing this provision without modification.

(3) SNF/NF Beds Expansion Intervention Payments

CMS waives 42 CFR 485.620(a), 42 CFR 485.645(a)(2), and section 1820(c)(2)(B)(iii) of the Act which limit CAHs to maintaining no more than 25 inpatient beds, including beds available for acute inpatient or swing bed services. CMS waives 1820(f) of the Act permitting designating or certifying a facility as a critical access hospital for which the facility at any time is furnishing inpatient beds which exceed more than 25 beds. Under this waiver, if the participating CAH has received swing bed approval from CMS, the participating CAH may maintain up to ten additional beds (for a total of 35 beds) available for acute inpatient or swing bed services; however, the participating CAH may only use these 10 additional beds for nursing facility or skilled nursing facility level of care. CMS would pay the participating CAH 101 percent of reasonable costs for its SNF/NF services furnished in the 10 additional beds. We received no comments on this proposal and therefore are finalizing this provision without modification.

d. Budget Neutrality

(1) Budget Neutrality Requirement

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), we finalized a policy to address the budget neutrality requirement for the demonstration initial period. We also discussed this policy in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 through 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58996). As explained in the FY 2022 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration initial period of performance in the FY 2022 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

For the FY 2023 proposed rule, we proposed to adopt the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110 275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period are not sufficiently offset by reductions elsewhere, we would recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration initial period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2022 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2022 IPPS/LTCH PPS final rule, we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Under the policy finalized in the FY 2022 IPPS/LTCH PPS final rule, we adopted the policy finalized in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration initial period was found not to have been budget neutral, any excess costs would be recouped over a period of 3 cost reporting years. In the FY 2023 IPPS/LTCH PPS proposed rule, we sought public comment on this proposal, since we were revising an aspect of the policy finalized in the FY 2022 IPPS/LTCH PPS final rule. Our new proposed policy is in the event the demonstration extension period is found not to have been budget neutral, any excess costs would be recouped within one fiscal year. We believe our new policy is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data and/or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period. We

received no comments on this proposal and therefore are finalizing this provision without modification.

(2) FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to adopt the budget neutrality methodology and analytical approach used during the demonstration initial period to ensure budget neutrality for the extension period. The analysis of budget neutrality during the initial period of the demonstration identified both the costs related to providing the intervention services under the FCHIP Demonstration and any potential downstream effects of the intervention-related services, including any savings that may have accrued.

The budget neutrality analytical approach for the demonstration initial period incorporated two major data components: (1) Medicare cost reports; and (2) Medicare administrative claims. As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS computed the cost of the demonstration for each fiscal year of the demonstration initial period using Medicare cost reports for the participating CAHs, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention services.

In addition, in order to capture the full impact of the interventions, CMS developed a statistical modeling, Difference-in-Difference (DiD) regression analysis to estimate demonstration expenditures and compute the impact of expenditures on the intervention services by comparing cost data for the demonstration and non-demonstration groups using Medicare administrative claims across the demonstration period of performance under the initial period of the demonstration. The DiD regression analysis would compare the direct cost and potential downstream effects of intervention services, including any savings that may have accrued, during the baseline and performance period for both the demonstration and comparison groups.

Second, the Medicare administrative claims analysis would be reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. We would estimate the costs of the demonstration using ''as submitted'' cost reports for each hospital's financial fiscal year participation within each of the demonstration extension period performance years. Each CAH has its own Medicare cost report end date applicable to the 5-year period of performance for the demonstration extension period. The cost report is structured to gather costs, revenues and statistical data on the provider's financial fiscal period. As a result, we would determine the final budget neutrality results for the demonstration extension once complete data is available for each CAH for the demonstration extension period. We received no comments on this proposal and therefore are finalizing this provision without modification.

d. Policies for Implementing the 5-Year Extension and Provisions Authorized By Section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260)

As stated in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to be used for the demonstration extension period.

Comment: A commenter expressed support of CMS implementation of the FCHIP demonstration initial period of performance, the demonstration intervention payment waivers and of the budget neutrality methodology for the extension period. The commenter urged CMS to continue implementing the five-year extension period of the demonstration project with the same budget neutrality and analytical approach as it used in the demonstration initial period. In addition, the commenter requested that CMS increase the number of CAHs participating in the demonstration extension period. The commenter explained that several other CAH service areas have unique topography that could benefit by participation in the demonstration extension period, specifically, special consideration should be granted to allow additional participants within the demonstration ambulance service intervention.

Response: We appreciate the commenter's support of the demonstration project and the budget neutrality methodology. We acknowledge the commenter's request for CMS to expand the number of CAHs participating in the demonstration extension period. However, we note that section 129(b)(C) of Public Law 116–260, stipulates ''[a]n entity shall only be eligible to participate in the demonstration project under this section during the extension period if the entity participated in the demonstration project under this section during the initial period.'' As such, expanding the number of CAHs participating within the demonstration extension period would require legislative action to the eligible entities, as defined in section 129(b)(C) of Public Law 116–260. After consideration of the public comments we received, we are finalizing our proposal to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to be used for the demonstration extension period without modification.

e. Total Budget Neutrality Offset Amount for FY 2023

At this time, for the FY 2023 IPPS/LTCH PPS proposed rule, while this discussion represents our anticipated approach to assessing the financial impact of the demonstration extension period based on upon receiving data for the full demonstration extension period, we may update and/or modify the FCHIP Demonstration budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

Therefore, we did not propose to apply a budget neutrality payment offset to payments to CAHs in FY 2023. This policy will have no impact for any national payment system for FY 2023. We received no comments on this proposal and therefore are finalizing this provision without modification.

VIII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2023

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital that has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act also provided an alternative definition of LTCHs (''subclause II'' LTCHs). However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals,'' to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resource use and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through 2007), the system used information from LTCH patient records to classify patients into distinct long-term care-diagnosis-related groups (LTCDRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity-long-term care-diagnosis related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable-cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this final rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate. In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to 82 FR 38299.)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-percent threshold policy under 42 CFR 412.538, which was a payment adjustment that was applied to

payments for Medicare patient LTCH discharges when the number of such patients originating from any single referring hospital was in excess of the applicable threshold for given cost reporting period.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b1 (note)) (Statewide-all payer systems, subject to the rate-of increase test at section 1814(b) of the Act), or section 3201 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

4. Best Available Data

We refer readers to section I.F. of the preamble of this final rule for our discussion on our use of the most recent data available for the FY 2023 LTCH PPS ratesetting, including the FY 2021 MedPAR claims and FY 2020 cost report data. In section I.F. of the preamble of this final rule we also discuss our modification of our ratesetting methodology for FY 2023 to account for the ongoing COVID–19 PHE.

Comment: We received several comments unrelated to LTCH PPS proposals included in the proposed rule. For example, some commenters requested changes to the structure of the site neutral payment policy or the calculation of the average length of stay.

Response: We appreciate the commenters' feedback and will keep these comments in mind for future rulemaking.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2023

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

Under both the IPPS and the LTCH PPS, the DRG-based classification system uses information on the claims for inpatient discharges to classify patients into distinct groups (for example, DRGs) based on clinical characteristics and expected resource needs. When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. We referred to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), we adopted the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O, applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion

in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. As noted previously, we adopted the same DRG patient classification system utilized at that time under the IPPS. The MS–DRG classifications are updated annually, which has resulted in the number of MS–DRGs changing over time. For FY 2023, there will be 767 MS–DRG, and by extension, MS–LTC–DRG, groupings based on the changes, as discussed in section II.E. of the preamble of this final rule.

Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA. That is, we assign an appropriate weight to the MS–LTC–DRGs to account for the differences in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCH patients.

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs) or are minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim. Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using the version ASC X12 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in subparts I through S of part 162. Among other requirements, on or after January 1, 2012, covered entities are required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code sets when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.E.1. of the preamble of this final rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain types of cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Changes to the MS–LTC–DRGs for FY 2023

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this final rule, as proposed, we updated the MS–LTC–DRG classifications effective October 1, 2022 through September 30, 2023 (FY 2023) consistent with the changes to specific MS–DRG classifications presented in section II.D. of the preamble of this final rule. Accordingly, the MS–LTC–DRGs for FY 2023 are the same as the MS–DRGs being used under the IPPS for FY 2023. In addition, because the MS–LTC–DRGs for FY 2023 are the same as the MS–DRGs for FY 2023, the other changes that affect MS–DRG (and, by extension, MS–LTC–DRG) assignments under GROUPER Version 40, as discussed in section II.D. of the preamble of this final rule, including the changes to the MCE software and the ICD–10–CM/PCS coding system, are also applicable under the LTCH PPS for FY 2023.

3. General Summary of the FY 2023 MS–LTC–DRG Relative Weights Methodology

In this section of this final rule, we provide a general summary of our modifications to the methodology for determining the FY 2023 MS–LTC–DRG relative weights under the LTCH PPS.

a. Averaging of Relative Weights for FY 2023

In section I.F. of the preamble to this final rule, we discuss our use of FY 2021 claims data for the FY 2023 LTCH PPS ratesetting. As we discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28466), we recognize the impact COVID–19 cases in the FY 2021 claims data have on the relative weight calculations for a few COVID–19-related MS–LTC–DRGs. Specifically, we have determined that the COVID–19 cases grouped to a few MS–LTC–DRGs have, on average, meaningfully different costs than the non-COVID–19 cases grouped to these MS–LTC–DRGs. As a result, for these MS–LTC–DRGs, the relative weights calculated using all cases will be meaningfully different than the relative weights calculated excluding COVID–19 cases. For example, using the FY 2021 MedPAR data, the relative weight for MS–LTC–DRG 870 (Septicemia or severe sepsis with MV >96 hours) is approximately 3.1 percent higher when the relative weights are calculated including COVID–19 cases compared to when the relative weights are calculated excluding COVID–19 cases.

In section I.F. of the preamble to this final rule, we also discuss that we believe it is reasonable to assume there will be fewer COVID–19 hospitalizations among Medicare beneficiaries in LTCHs in FY 2023 than there were in FY 2021, although we cannot know the actual number of COVID–19 hospitalizations among Medicare beneficiaries in LTCHs in FY 2023. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28466), we proposed to modify our relative weight methodology for FY 2023 to align with an assumption that there will be fewer, but not zero, COVID–19 cases in FY 2023 compared to FY 2021. To account for this assumption, we proposed an averaging approach to determine the MS–LTC–DRG relative weights for FY 2023. Specifically, we proposed to calculate the relative weights both including and excluding COVID–19 cases, and then average the two sets of relative weights together. We stated our belief that this would be appropriate as it would reduce, but not remove entirely, the effect of COVID–19 cases on the relative weight calculations, particularly given the uncertainty in the number of COVID–19 cases in FY 2023. By averaging the relative weights in this manner, we stated our belief that the result would reflect a reasonable estimation of the mix of cases for FY 2023 based on the information available at the time on the trajectory of the COVID–19 PHE (as discussed in section I.F. of the preamble to this final rule), and a more accurate estimate of the relative resource use for cases treated in FY 2023. We believe the relative weights calculated using our modified methodology would be more accurate than if we applied our standard methodology, that is, with relative weights calculated based on 100 percent of the relative weights calculated using all applicable LTCH cases. As discussed in section I.O of Appendix A of the proposed rule, as an alternative to our proposed approach, we considered following our historical approach for calculating the relative weights and not proposing this modification. That is, we considered determining the FY 2023 MS–LTC–DRG weights using all applicable LTCH cases without any modifications to account for COVID–19 cases.

Comment: We received comments that were supportive of our proposal to use FY 2021 data when determining the FY 2023 MS–LTC–DRG relative weights. We also received comments that were supportive of our proposal to calculate the relative weights both including and excluding COVID–19 cases, and then averaging the two sets of relative weights together. A commenter stated that this is a sensible approach to account for the effects of COVID–19 on the data CMS uses for ratesetting.

Some commenters disagreed with the proposed approach for determining the FY 2023 MS–LTC–DRG relative weights. These commenters believe a more appropriate approach would be to determine the relative weights based on an average of the relative weights calculated using FY 2019 data and FY 2021 data. These commenters stated that COVID–19 has not only influenced LTCH costs of care through higher direct input costs, but also through other factors such as challenges in discharging patients. Since it is uncertain whether these factors will remain in FY 2023, these commenters believe their suggested approach, which blends claims data prior to the PHE with claims data during the PHE, better reflects the overall uncertainty of the future impact of COVID–19.

We did not receive any comments in support of the alternative approach that we discussed in section I.O of Appendix A of the proposed rule.

Response: We thank the commenters for their support. With respect to the commenters who suggested we determine the relative weights based on an average of the relative weights calculating using FY 2019 and FY 2021 data, we recognize that there is uncertainty regarding the utilization and costs that LTCHs will experience in FY 2023. While the commenters' approach for addressing this uncertainty is not unreasonable, we believe that our proposed approach will result in a more accurate reflection of the types of cases expected to be treated by LTCHs in FY 2023. Specifically, we believe that the mix and resource use of non-COVID–19 cases is better represented by more recent MedPAR claims data than is

reflected in the cases in the FY 2019 data. Therefore, while we considered this alternative approach, we continue to believe that the relative weights determined as an average of the relative weights calculated with and without the COVID–19 cases reflected in the FY 2021 MedPAR data are a more reasonable estimation of the mix and relative resource use of cases that will be treated at LTCHs in FY 2023.

Therefore, after consideration of the public comments we received, we are finalizing our proposal to use FY 2021 MedPAR claims data to calculate the FY 2023 MS–LTC–DRG relative weights. We also are finalizing our proposal to establish the FY 2023 MS–LTC–DRG relative weights as an average of the relative weights calculated both including and excluding COVID–19 cases identified in the FY 2021 MedPAR claims. The technical details of the relative weight calculations are discussed in section VIII.B.4. of the preamble to this final rule. We note this averaging approach for the calculation of the FY 2023 MS–LTC–DRG relative weights is consistent with the approach being adopted under the IPPS for FY 2023, as discussed in section II.E.c. of the preamble to this final rule.

b. Cap on Relative Weight Decreases

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28466 through 28467), we discussed comments we have received in recent years about significant fluctuations in the relative weights for some MS–LTC–DRGs. We stated that some commenters have requested that CMS establish a transition policy to mitigate the negative effects of significant year-to-year reductions to relative weights. We stated that predictability and stability of rates is one of the fundamental principles of a prospective payment system. Instability in the relative weights for MS–LTC–DRGs can reduce the predictability and stability of an individual LTCH's Medicare payments from year to year. Therefore, given the concerns commenters have raised about the financial impacts of significant year-to-year fluctuations in MS–LTC–DRGs relative weights, we proposed a policy to address these concerns.

Consistent with the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, including adjustments to DRG weights, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28466 through 28467), we proposed to establish a permanent 10-percent cap on the reduction to a MS–LTC–DRG's relative weight in a given year, beginning in FY 2023. We proposed that this 10-percent cap would be applied to the relative weights for MS–LTC–DRGs with applicable LTCH cases. Under this policy, the 10-percent cap would not apply to no-volume MS–LTC–DRGs (that is, an MS–LTC–DRG with no applicable LTCH cases) whose relative weight was determined by a cross-walk to another MS–LTC–DRG's relative weight. We stated our belief that it is not necessary to apply the 10-percent cap to no-volume MS–LTC–DRGs because the financial impact of fluctuations in the relative weights for these no-volume MS–LTC–DRGs is extremely small, as evident by there being zero applicable LTCH cases grouped to these MS–LTC–DRGs in the MedPAR claims data.

We also proposed that the 10-percent cap on the reduction in a MS–LTC–DRG's relative weight in a given year be budget neutral, meaning we would apply a budget neutrality adjustment to the MS–LTC–DRG relative weights, after application of the 10-percent cap, to ensure that our proposed 10-percent cap on relative weight reductions policy results in no change in aggregate LTCH PPS standard Federal rate payments. We stated that our application of the proposed 10-percent cap on the reduction in a MS–LTC–DRG's relative weight in a given year in a budget neutral manner is consistent with the existing budget neutrality requirement for annual MS–LTC–DRG reclassification and recalibration, which we adopted to mitigate estimated fluctuations in estimated aggregate LTCH PPS payments (72 FR 26881–26882).

In the proposed rule, we stated our belief that the impact of the application of a cap on relative weight reductions on an LTCH's total LTCH PPS payments in a given year would be relatively small because a change in the relative weight would be applied to a single MS–LTC–DRG, unlike the impact of the wage index adjustment, which adjusts the payment for each discharge and impacts approximately two-thirds of an LTCH's total LTCH PPS payments in a given year. In considering the amount of the cap for our proposal, we explained that we balanced the number of MS–LTC–DRGs that would receive the cap with the magnitude of the budget neutrality factor that would be applied to all MS–LTC–DRGs, while also maintaining an accurate reflection of the relative resource use across the MS–LTC–DRG weights overall. We considered that a higher cap, such as 20-percent cap, would limit declines in the relative weights for fewer MS–LTC–DRGs while a lower cap, such as a 5-percent cap, would limit declines in the relative weights for more MS–LTC–DRGs, but would also result in a larger budget neutrality adjustment. We stated our belief that on balance, a 10-percent cap would mitigate financial impacts resulting from fluctuations in the relative weights, particularly for low-volume MS–LTC–DRGs, without the larger budget neutrality adjustment associated with a smaller cap, and without distorting the integrity of the MS–LTC–DRG relative weights overall as a reflection of relative resource use.

We noted that this proposed 10-percent cap on reductions to a MS–LTC–DRG's relative weight would apply only to a given MS–LTC–DRG with its current MS–LTC–DRG number. In cases where CMS creates new MS–LTC–DRGs or modifies existing MS–LTC–DRGs as part of its annual reclassifications resulting in renumbering of one or more MS–LTC–DRGs, we proposed that this limit on the reduction in the relative weight would not apply to any MS–LTC–DRGs affected by the renumbering (that is, the 10-percent cap would not apply to the relative weight for any new or renumbered MS–LTC–DRGs for the fiscal year).

Comment: Commenters generally agreed with our proposal to cap MS–LTC–DRG relative weights decreases at 90 percent of the value of the MS–LTC–DRG relative weight in the previous year. However, several commenters questioned the appropriateness of applying a budget neutrality adjustment to the 10-percent cap on relative weight reductions. These commenters expressed concern that the budget neutrality adjustment could result in a decrease to the relative weights for the most commonly used MS–LTC–DRGs (the ''high-volume'' MS–LTC–DRGs).

Although none of the proposed relative weights for the top five high volume MS–LTC–DRGs would decrease by more than 10-percent in FY 2023, commenters noted, the proposed budget neutrality adjustment to offset the 10-percent cap on relative weight decreases for other MS–LTC–DRGs will reduce the relative weights for these five most commonly used MS–LTC–DRGs. A commenter stated that ''high-volume'' MS–LTC–DRGs are less likely than ''low-volume'' MS–LTC–DRGs to decrease more than 10-percent, in which case applying the proposed 10-percent cap in a budget neutral manner would generally result in increases to the relative weights of low-volume MS–LTC–DRGs at the expense of decreases to the relative weights of high-volume MS–LTC–DRGs. A commenter recommended that CMS should only apply the 10-percent cap to an MS–

LTC–DRG relative weight if it is one of the top five MS–LTC–DRGs, by volume, of LTCH discharges. This, the commenter stated, would target payment relief where it is most needed and would have more of a beneficial effect on payment stability from year to year.

A number of commenters who disagreed with applying a budget neutrality adjustment to relative weights after application of the 10-percent cap maintained that CMS has the statutory authority to make adjustments, including waiving the budget neutrality adjustment to the cap, under section 123 of the BBRA, as amended by section BIPA 307(b)(1).

Response: We appreciate the comments in support of the proposed 10-percent cap on MS–LTC–DRG relative weight decreases. We agree that CMS has the statutory authority to implement this policy in a non-budget neutral manner. However, we continue to believe it is appropriate to implement this policy in a budget neutral manner, consistent with the existing budget neutrality requirement for annual MS–LTC–DRG reclassification and recalibration, which we adopted to mitigate estimated fluctuations in estimated aggregate LTCH PPS payments (72 FR 26881–26882).

However, we understand commenters' concerns regarding potential negative impacts of the budget neutrality adjustment on the highest volume MS–LTC–DRG relative weights. We recognize, as commenters stated, that the application of a 10-percent cap on decreases in MS–LTC–DRG relative weights, applied in a budget neutral manner, may inadvertently partially negate our stated intent to stabilize and increase predictability to LTCH payments. In response to these concerns, we conducted additional analysis regarding the cap on MS–LTC–DRG weights and the impact of the budget neutrality adjustment. Based on the March 2022 update of the FY 2021 MedPAR file used for calculating the MS–LTC–DRG relative weights in this final rule, under our proposal, 139 MS–LTC–DRGs would be subject to the 10-percent cap in FY 2023.

These 139 MS–LTC–DRGs accounted for approximately 5.1 percent of all standard Federal payment rate cases in FY 2021. After application of the cap to these 139 MS–LTC–DRGs, the budget neutrality adjustment, based on the data used for this final rule, would have reduced the relative weights of all MS–LTC–DRGs by 0.34 percent. We note that the proposed budget neutrality adjustment we calculated in the proposed rule was similar in magnitude and reduced the proposed relative weights by 0.33 percent. When developing this policy for the proposed rule, we considered the magnitude of the proposed budget neutrality adjustment against the overall benefits of our stated policy goal. As discussed in the proposed rule and noted previously, we believed the proposed policy would provide LTCHs more predictable and stable MS–LTC–DRG relative weights from year to year. When we made our proposal, it was our belief that the overall benefits of the policy would outweigh the effect of the corresponding budget neutrality adjustment on the MS–LTC–DRG relative weights. However, based on public comments received, it clear that not all commenters share this belief.

Therefore, we have explored whether placing a limit on MS–LTC–DRGs subject to the cap, similar to the approach suggested by a commenter, would reduce both the number of MS–LTC–DRGs capped and the size of the budget neutrality adjustment. We found that limiting the application of the 10-percent cap to MS–LTC–DRGs with at least 25 cases resulted in a significant decrease to the number of MS–LTC–DRGs subject to the cap, from 139 to 25. The MS–LTC–DRGs capped under such policy accounted for 3.9 percent of all standard Federal payment rate cases in FY 2021, and the associated budget neutrality adjustment for this cap would result in a much smaller reduction to the relative weights of all MS–LTC–DRGs (that is, −0.13 percent).

We believe that modifying our proposed policy so that the 10-percent cap on MS–LTC–DRG relative weight decreases only applies to MS–LTC–DRGs with 25 or more cases addresses commenters' concerns about the destabilizing impact of the budget neutrality adjustment, as the budget neutrality adjustment associated with this more limited cap policy (−0.13 percent reduction to the relative weights) is meaningfully less than the budget neutrality adjustment associated with our proposed cap policy. We believe that 25 cases is an appropriate threshold since that threshold is already used in establishing the low-volume MS–LTC–DRGs that are grouped into quintiles for purposes of calculating the MS–LTC–DRG relative weights (As discussed in section VIII.B.4. of the preamble to this final rule, for purposes of calculating the MS–LTC–DRG relative weights, we group low-volume MS–LTC–DRGs, that is those MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases, into five categories (quintiles) based on average charges). We also believe that modifying our proposed policy to limit the application of the 10-percent cap to MS–LTC–DRGs with 25 or more cases will still result in more predictable and stable MS–LTC–DRG relative weights from year to year, especially for high-volume MS–LTC–DRGs that generally have the largest financial impact on an LTCH's operations. We note that this modification to our 10-percent cap policy will treat MS–LTC–DRGs with 1–24 cases (low-volume MS–LTC–DRGs) the same as we proposed to treat no-volume MS–LTC–DRGs. That is, the 10-percent cap will not apply to either MS–LTC–DRGs with 1–24 cases (low-volume) or no-volume MS–LTC–DRGs.

Comment: MedPAC, while agreeing with the proposal to cap decreases in MS–LTC–DRG weights at 90 percent of the MS–LTC–DRG relative weight from the previous year, recommended extending this policy to MS–LTC–DRG relative weights increasing by more than 10 percent, as well.

Response: We appreciate the suggestion that the cap should apply to increases in MS–LTC–DRG relative weights as well as decreases. However, as we discussed in the proposed rule, our goal in smoothing year-to-year changes in MS–LTC–DRG relative weights is to increase predictability for LTCHs to enable them to better plan; when hospitals have more time to adjust to significant changes to relative weights, they can mitigate financial impacts. We did not propose to limit increases in MS–LTC–DRG relative weights because we do not believe such a policy is needed to enable hospitals to more effectively budget and plan their operations.

In this final rule, after consideration of public comments received, we are finalizing our proposed policy to cap decreases in MS–LTC–DRG relative weights to 10 percent of the previous year's relative weight, with a modification that limits the application of the cap to only MS–LTC–DRGs with at least 25 applicable LTCH cases in the claims data used to calculate the relative weights for the fiscal year. We also are finalizing our proposal that the 10-percent cap on the reduction in a MS–LTC–DRG's relative weight in a given year will be budget neutral. As an example, if the relative weight for an MS–LTC–DRG with at least 25 applicable LTCH cases was 1.100 in FY 2022 and the relative weight for FY 2023 would otherwise be 0.9350, which would represent a decrease of 15 percent from FY 2022, the reduction would be limited to 10 percent such that the relative weight for FY 2023 would be 0.9900 (that is, 0.90 × FY 2022 weight of 1.100) prior to the application of the

budget neutrality adjustment (as described later in this section in Step 13 of our methodology). In cases where CMS creates new MS–LTC–DRGs or modifies the MS–LTC–DRGs as part of its annual reclassifications resulting in renumbering of one or more MS–LTC–DRGs, we are finalizing our proposal that this the 10-percent cap will not apply to the relative weight for any new or renumbered MS–LTC–DRGs for the fiscal year.

Consequently, we are amending our proposed regulation at 42 CFR 412.515 to reflect the modification we are adopting in this final rule to limit the application of the 10-percent cap on MS–LTC–DRG relative weight reductions to only MS–LTC–DRGs with at least 25 applicable LTCH cases in the claims data used to calculate the relative weights for the fiscal year. The technical details of this provision are discussed in section VIII.B.4. of the preamble to this final rule. We note that this provision is similar to the permanent 10-percent cap on decreases to a MS–DRG relative weight being adopted under the IPPS, as discussed in section II.E.d. of the preamble of this final rule.

c. Conforming Changes to Other Components of the FY 2023 MS–LTC–DRG Relative Weights Methodology

In general, for FY 2023, we continue to apply the other components of our existing methodology for determining the MS–LTC–DRG relative weights (as discussed in greater detail in section VIII.B.4. of the preamble of this final rule) that are not impacted by our previously described modifications to our methodology. As discussed previously, we are establishing the FY 2023 MS–LTC–DRG relative weights using an average of the relative weights calculated both including and excluding the COVID–19 claims to align with an assumption that there will be fewer, but not zero, COVID–19 cases in FY 2023 compared to FY 2021. We note that in conjunction with this modification, we applied the MS–LTC–DRG relative weights methodology, described later in this section, twice—once to determine the relative weights based on claims data that include COVID–19 cases and again to determine the relative weights based on claims data that exclude COVID–19 cases. Specifically, in determining the relative weights based on both sets of claims, we applied our established policies related to the hospital-specific relative value methodology, the treatment of severity levels in the MS LTC DRGs, low-volume and no-volume MS LTC DRGs, and adjustments for nonmonotonicity, only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate). We discuss all components of our MS–LTC–DRG relative weight methodology in greater detail in section VIII.B.4.g. of the preamble of this final rule.

4. Development of the FY 2023 MS–LTC–DRG Relative Weights

a. General Overview of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume or nonmonotonicity or both resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and nonmonotonicity or both, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617).

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–LTC–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section in Step 3 of our methodology) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described later in this section in Step 8 of our methodology). For FY 2023, we are continuing to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2023 MS–LTC–DRG relative weights.

As discussed in section VIII.B.3.a. of the preamble to this final rule, for FY 2023, we are establishing the MS–LTC–DRG relative weights as an average of the relative weights calculated both including and excluding the COVID–19 claims. As discussed in section VIII.B.3.b. of the preamble to this final rule, we also are establishing a 10-percent cap on the reduction in a MS-LTC–DRG's relative weight, beginning in FY 2023 for MS–LTC–DRGs with at least 25 applicable LTCH cases in the claims data used to calculate the relative weights for the fiscal year.

b. Development of the MS–LTC–DRG Relative Weights for FY 2023

In this section, we present our methodology for determining the MS–LTC–DRG relative weights for FY 2023. In general, we are continuing to apply the components of our existing methodology that are not impacted by our modifications to use an average of the relative weights calculated both including and excluding the COVID–19 claims and the application of a 10-percent cap on the reduction in a MS–LTC–DRG's relative weight, as discussed in section VIII.B.3 of the preamble to this final rule. For example, we are continuing with the application of established policies related to the hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate). We note that in our establishment of MS–LTC–DRG relative weights using an average of the relative weights calculated both including and excluding the COVID–19 claims, particular components of our existing relative weight methodology are performed twice (once when determining relative weights based on claims data that include COVID–19 cases and again when determining relative weights based on claims data that exclude COVID–19 cases). Later in this section we list and provide a brief description of our steps for determining the FY 2023 MS–LTC–DRG relative weights. Each step is discussed in greater detail later in this section.

• *Step 1—Prepare data for MS–LTC–DRG relative weight calculation.* In this step, we select and group the applicable claims data used in the development of the MS–LTC–DRG relative weights. For FY 2023, we are preparing two sets of claims: a claims dataset that includes COVID–19 cases and a claims dataset that excludes COVID–19 cases.

• *Step 2—Remove cases with a length of stay of 7 days or less.* In this step, we trim the applicable claims data to remove cases with a length of stay 7 days or less. For FY 2023, we are performing this step on each set of claims data (claims dataset that includes COVID–19 cases and claims dataset that excludes COVID–19 cases).

• *Step 3—Establish low-volume MS–LTC–DRG quintiles.* In this step, we employ our established quintile methodology for low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases). For FY 2023, we are performing this step on each set of claims data (claims dataset that includes COVID–19 cases and claims dataset that excludes COVID–19 cases).

• *Step 4—Remove statistical outliers.* In this step, we trim the applicable claims data to remove statistical outlier cases. For FY 2023, we are performing this step on each set of claims data (claims dataset that includes COVID–19 cases and claims dataset that excludes COVID–19 cases).

• *Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).* In this step, we adjust the number of applicable cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases. For FY 2023, we are performing this step on each set of claims data (claims dataset that includes COVID–19 cases and claims dataset that excludes COVID–19 cases).

• *Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative weights methodology.* In this step, we use our established hospital-specific relative value (HSRV) methodology, which is an iterative process, to calculate the relative weights. For FY 2023, we are using the HSRV methodology to calculate relative weights using the claims that include COVID–19 cases and again using the claims that exclude the COVID–19 cases.

• *Step 7— Adjust the relative weights to account for nonmonotonically increasing relative weights.* In this step, we make adjustments that ensure that within each base MS–LTC–DRG, the relative weights increase by MS–LTC–DRG severity. For FY 2023, we are adjusting each set of relative weights (that is, the relative weights calculated including COVID–19 cases and the relative weights calculated excluding COVID–19 cases).

• *Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases.* In this step, we cross-walk each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight. For FY 2023, we are cross-walking no-volume MS–LTC–DRGs in each set of relative weights (that is, the set of relative weights calculated including COVID–19 cases and the set of relative weights calculated excluding COVID–19 cases).

• *Step 9—Normalize each set of relative weights.* In this step, we make a normalization adjustment so that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index. For FY 2023, we are normalizing the set of relative weights calculated including COVID–19 cases and the set relative weights calculated excluding COVID–19 cases.

• *Step 10—Average the two sets of normalized relative weights.* In this step, we average the set of normalized relative weights calculated including COVID–19 cases and the set of normalized relative weights calculated excluding COVID–19 cases. In addition to the relative weights, we also average the geometric mean length of stays and arithmetic mean length of stays.

• *Step 11—Budget neutralize the averaged relative weights.* In this step, to ensure budget neutrality in the annual update to the MS–LTC–DRG classifications and relative weights, we adjust the relative weights by a normalization factor and budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by the updates to the MS–LTC–DRG classifications and relative weights. This step is performed prior to applying the 10-percent cap.

• *Step 12—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights.* In this step we limit the reduction of the relative weight for a MS–LTC–DRG to 10 percent of its prior year value. This 10-percent cap does not apply to zero-volume MS–LTC–DRGs or low-volume MS–LTC–DRGs.

• *Step 13—Calculate the MS–LTC–DRG cap budget neutrality factor.* In this step, to ensure budget neutrality in the application of the MS–LTC–DRG cap policy, we adjust the relative weights by a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by our application of the cap to the MS–LTC–DRG relative weights.

Later in this section we describe each of the 13 steps for calculating the FY 2023 MS–LTC–DRG relative weights in greater detail. In this discussion, we note when the step was performed twice under our provisions for averaging relative weights calculated including COVID–19 cases and relative weights calculated excluding COVID–19 cases.

Step 1—Prepare data for MS–LTC–DRG relative weight calculation.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28469), consistent with our proposals regarding the calculation of the proposed MS–LTC–DRG relative weights for FY 2023, we obtained total charges from FY 2021 Medicare LTCH claims data from the December 2021 update of the FY 2021 MedPAR file, which was the best available data at that time, and we proposed to use Version 40 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we proposed that if better data became

available, we would use those data and the finalized Version 40 of the GROUPER in establishing the FY 2023 MS–LTC–DRG relative weights in the final rule. Accordingly, for this final rule, we are establishing the FY 2023 MS–LTC–DRG relative weights based on updated FY 2021 Medicare LTCH claims data from the March 2022 update of the FY 2021 MedPAR file, which is the best available data at the time of development of this final rule, and the finalized Version 40 of the GROUPER to classify LTCH cases.

To calculate the FY 2023 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, as we proposed, we continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the March 2022 update of the FY 2021 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) or had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2021 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or
- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2021 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion. We note that we have previously addressed the treatment of cases that would have been excluded from the site neutral payment rate under the statutory provisions that provided for temporary exception from the site neutral payment rate under the LTCH PPS for certain spinal cord specialty hospitals or for certain severe wound care discharges from certain LTCHs provided by sections 15009 and 15010 of Public Law 114–255, respectively. These statutory provisions were not in effect for any discharges occurring in FY 2021 (or beyond), so it is no longer necessary to address their treatment for purposes of developing the MS–LTC–DRG relative weights. We also note that section 3711(b)(2) of the CARES Act, which provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period, was in effect for the entirety of FY 2021. Therefore, all LTCH PPS cases in FY 2021 were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. However, for purposes of setting rates for LTCH PPS standard Federal rate cases for FY 2023 (including MS–LTC–DRG relative weights), we used FY 2021 cases that meet the statutory patient criteria without consideration to how those cases were paid in FY 2021.

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files.

In addition, as discussed in section VIII.B.3.a. of this final rule, for FY 2023, we are establishing the MS–LTC–DRG relative weights as an average of the relative weights calculated both including and excluding the COVID–19 claims. To calculate the set of relative weights based on claims that excluded COVID–19 cases, we performed an additional trim to remove COVID–19 cases. We identified COVID–19 cases as any claim in the FY 2021 MedPAR file with a principal or secondary diagnosis of COVID–19 (ICD–10–CM diagnosis code U07.1).

In summary, in general, we identified the claims data used in the development of the FY 2023 MS–LTC–DRG relative weights in this final rule by trimming claims data that would have been paid the site neutral payment rate had the provisions of the CARES Act not been in effect. We trimmed the claims data of all-inclusive rate providers reported in the March 2022 update of the FY 2021 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the March 2022 update of the FY 2021 MedPAR file, but, had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy.

We used the remaining data (that is, the applicable LTCH data) in the subsequent steps to calculate the set of relative weights based on claims that include COVID–19 cases. In addition, we performed a trim to remove COVID–19 cases based on a principal or secondary diagnosis of COVID–19. We used these data in the subsequent steps to calculate the set of relative weights based on claims that exclude COVID–19 cases.

Step 2—Remove cases with a length of stay of 7 days or less.

The next step in our calculation of the FY 2023 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the FY 2023 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, as we proposed, consistent with our existing relative weight methodology, in determining the FY 2023 MS–LTC–DRG relative weights, we removed LTCH cases with a length of stay of 7 days or less from applicable LTCH cases for both sets of claims (that is the applicable LTCH claims that include COVID–19 cases and the applicable LTCH claims that exclude COVID–19 cases). (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3—Establish low-volume MS–LTC–DRG quintiles.

To account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, as we proposed, we are continuing to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)). Under our provision in section VIII.B.3.a. of the preamble to this final rule to establish the FY 2023 MS–LTC–DRG relative weights as an average of the relative weights calculated both including and excluding the COVID–19 claims, we employed our quintile methodology when calculating the relative weights for each set of claims (that is the claims that include COVID–19 cases and the claims that exclude COVID–19 cases).

In this final rule, based on the best available data (that is, the March 2022 update of the FY 2021 MedPAR files), we identified 233 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases in the claims data that included COVID–19 cases, and 232 MS LTC–DRGs that contained between 1 and 24 applicable LTCH cases in the claims data that excluded COVID–19 cases. These lists of MS–LTC–DRGs were then divided into 1 of the 5 low-volume quintiles. We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this final rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases in each set of claims was not evenly divisible by 5. The quintiles based on the claims data that included COVID–19 cases each contained at least 46 MS–LTC–DRGs (233/5 = 46 with a remainder of 3). Meanwhile, the quintiles based on the claims data that excluded COVID-cases also each contained at least 46 MS–LTC–DRGs (232/5 = 46 with a remainder of 2). We employed our historical methodology of assigning each remainder low-volume MS–LTC–DRG to the low-volume quintile that contains an MS–LTC–DRG with an average charge closest to that of the remainder low-volume MS–LTC–DRG.

For the claims that include COVID–19 cases, the application of our quintile methodology resulted in 2 low-volume quintiles containing 46 MS–LTC DRGs (Quintiles 1 and 5) and 3 low-volume quintiles containing 47 MS–LTC–DRGs (Quintiles 2, 3, and 4). For the claims that excluded COVID–19 cases, the application of our quintile methodology resulted in 3 low-volume quintiles containing 46 MS–LTC DRGs (Quintiles 1, 3, and 5) and 2 low-volume quintiles containing 47 MS–LTC–DRGs (Quintiles 2 and 4). In cases where these initial assignments of low-volume MS–LTC–DRGs to quintiles results in nonmonotonicity within a base-DRG, we are making adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in Step 7 of our methodology.

To determine the FY 2023 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, we used the five low-volume quintiles from each set of claims described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in Step 6 of our methodology. We assigned the same relative weight and average length-of-stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. These calculations were performed separately for the relative weight set based on claims that include COVID–19 cases and the relative weight set based on claims that exclude COVID–19 cases. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases would vary in the future.

Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases. In the proposed rule, we noted our description in previous rules did not specify the point in our methodology when the low-volume MS–LTC–DRG quintiles are established. We stated that although we are now including this step explicitly, this is not a change to our historical methodology for determining the MS–LTC–DRG relative weights.

For this final rule, we are providing the lists of the composition of the low-volume quintiles for low-volume MS–LTC–DRGs in a supplemental data file for public use posted via the internet on the CMS website for this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11. This supplemental data file includes the composition of low-volume quintiles for low-volume MS–LTC–DRGs based on the claims that include COVID–19 cases and the composition of the low-volume quintiles for low-volume MS–LTC–DRGs based on the claims that exclude COVID–19 cases.

Step 4—Remove statistical outliers.

The next step in our calculation of the FY 2023 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length-of-stay of at least 8 days. Consistent with our existing relative weight methodology, as we proposed, we are continuing to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use.

Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) This step was performed on both sets of claims (that is the applicable LTCH claims that include COVID–19 cases and the applicable LTCH claims that exclude COVID–19 cases). After removing cases with a length of stay of 7 days or less and statistical outliers, in each set of claims, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this final rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).

As the next step in the calculation of the FY 2023 MS–LTC–DRG relative weights, consistent with our historical approach, as we proposed, we adjusted each LTCH's charges per discharge for those remaining cases in each set of claims (that is, trimmed applicable LTCH cases that include COVID–19 cases and the trimmed applicable LTCH cases that exclude COVID–19 cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, as we proposed, we made this adjustment by counting an

SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay of all cases grouped to the MS–LTC–DRG. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the FY 2023 MS–LTC–DRG relative weights would lower the relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we are continuing to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative value (HSRV) methodology.

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2023 IPPS/LTCH PPS final rule, as we proposed, we are continuing to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2023. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduced the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs). In other words, by multiplying an LTCH's relative charge values by the LTCH's case-mix index, we account for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource-intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

Consistent with our historical relative weight methodology, as we proposed, we calculated the FY 2023 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. Under our provision in section VIII.B.3.a. of the preamble to this final rule to establish the FY 2023 MS–LTC–DRG relative weights as an average of the relative weights calculated both including and excluding the COVID–19 claims, we applied the HSRV methodology when calculating the relative weights for each sets of claims (that is the claims that include COVID–19 cases and the claims that exclude COVID–19 cases).

Therefore, in accordance with our established methodology, for FY 2023, we continued to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in Step 5 of our methodology) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The average adjusted charge was then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each MS–LTC–DRG, we calculated the FY 2023 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent cases from Step 5 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent applicable LTCH cases from Step 5 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values were then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary

diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the FY 2023 MS–LTC–DRG relative weights based on each set of claims (that is claims that include COVID–19 cases and the claims that exclude COVID–19 cases), consistent with our historical methodology, as we proposed, we continued to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). For both sets of weights, the one based on claims that include COVID–19 cases and the one based on claims that exclude COVID–19 cases, any adjustments for nonmonotonicity that were made in determining the FY 2023 MS–LTC–DRG relative weights by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website.

Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the MS–LTC–DRGs for which there were no claims in the March 2022 update of the FY 2021 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this final rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, as we proposed, we cross-walked each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' MS–LTC–DRG was assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of this final rule).

For this final rule, there was only one claim grouped to MS–LTC–DRG 273 (Percutaneous and other intracardiac procedures with MCC) in the March 2022 update of the FY 2021 MedPAR file. This claim had a COVID–19 diagnosis code. Therefore, when determining relative weights based on all applicable LTCH claims, a relative weight was computed for MS–LTC–DRG 273. However, when determining relative weights based on the set of claims that excluded COVID–19 cases, a relative was not computed for MS–LTC–DRG 273. When establishing the relative weights based on claims that exclude COVID–19 cases, instead of assigning a cross-walked relative weight for MS–LTC–DRG 273, as we proposed, we assigned MS–LTC–DRG 273 the relative weight calculated using all applicable LTCH cases. In the absence of a non-COVID–19 claim for this MS–LTC–DRG, we believe the relative weight based on a COVID–19 claim grouped to this same MS–LTC–DRG would more accurately reflect the relative resource use of this MS–LTC–DRG than a relative weight based on a cross-walked MS–LTC–DRG.

Of the 767 MS–LTC–DRGs for FY 2023, we identified 427 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. We do not include MS–LTC–DRG 273, discussed previously, in this count. The 427 MS LTC DRGs for which there were no trimmed applicable LTCH cases includes the 11 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed in this section of this rule, such that we identified 399 MS–LTC–DRGs that for which, we assigned a relative weight using our existing ''no-volume'' MS–LTC–DRG methodology (that is, $427 - 11 - 2 - 15 = 399$). As we proposed, we assigned relative weights to each of the 399 no-volume MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 340 ($767 - 427 = 340$) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2021 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as one of the 340 MS–LTC–DRGs to which we cross-walked each of the 399 ''no-volume'' MS–LTC–DRGs.) Then, in general, we assigned the 399 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG (when necessary, we made adjustments to account for nonmonotonicity).

We cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we calculated relative weights based on the March 2022 update of the FY 2021 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay.

(For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2023, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2023. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2023. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments are required to maintain monotonically increasing relative weights.)

For this final rule, we are providing the list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2023 in a supplemental data file for public use posted via the internet on the CMS website for this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the relative weights for the FY 2023 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example.

Example: There were no trimmed applicable LTCH cases in the FY 2021 MedPAR file that we are using for this final rule for MS–LTC–DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that MS–LTC–DRG 070 (Nonspecific cerebrovascular disorders with MCC) is similar clinically and based on resource use to MS–LTC–DRG 061. Therefore, we assigned the same relative weight (and average length of stay) of MS–LTC–DRG 70 of 0.837 for FY 2023 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume would vary in the future. Consistent with our historical practice, as we proposed, we used the best available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in the final rule.

For FY 2023, consistent with our historical relative weight methodology, as we proposed, we are establishing a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Simultaneous Pancreas/Kidney Transplant with Hemodialysis (MS–LTC–DRG 019); Pancreas Transplant (MS–LTC–DRG 010); Kidney Transplant (MS–LTC–DRG 652); Kidney Transplant with Hemodialysis with MCC (MS–LTC–DRG 650), and Kidney Transplant with Hemodialysis without MCC (MS LTC DRG 651). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these 11 transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are establishing a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, we are establishing a relative weight of 0.0000 for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). We are establishing a relative weight 0.0000 for these 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate would not be applicable for any LTCH discharges occurring in FY 2023, and as such payment under the LTCH PPS would be no longer be made in part based on the LTCH PPS standard Federal payment rate for any discharges assigned to those MS–LTC–DRGs.

Step 9—Normalize the two sets of relative weights.

The next step in our calculation of the FY 2023 MS–LTC–DRG relative weights is to normalize the set of relative weights that were calculated using claims that include COVID–19 cases and to normalize the set of relative weights that were calculated using claims that excluded COVID–19 cases. The normalization adjustment is intended to ensure that the recalibration of the MS–

LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index. To calculate the normalization factors, we grouped applicable LTCH cases from each set of claims using the FY 2023 Version 40 GROUPER, and used the FY 2023 MS–LTC–DRG relative weights associated with each set to calculate the average case-mix index (CMI) for each set; we grouped the same applicable LTCH cases from each set of claims using the FY 2022 GROUPER Version 39 and MS–LTC–DRG relative weights and calculated the average CMI for each set; and computed the ratio by dividing the average CMI for each set for FY 2022 by the average CMI for each set for FY 2023. These ratios are the normalization factors that were applied to each respective set of unnormalized weights. Because the calculation of the normalization factor involves the relative weights for the MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume MS–LTC–DRGs are included in the calculation (and the MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation). The table displays the normalization factors that were calculated and applied for each set of relative weights.

Claims used in Calculation	Normalization Factor
All applicable LTCH cases, including COVID-19 cases	1.33569
All applicable LTCH cases, excluding COVID-19 cases	1.33224

Step 10—Average the two sets of normalized relative weights.

After each set of relative weights was normalized, we computed a simple average of the normalized relative weights and geometric mean length of stays from each set, by using 50 percent of the relative weights calculated using applicable LTCH cases that include COVID–19 cases and 50 percent of the relative weights calculated using applicable LTCH cases that exclude COVID–19 cases.

Step 11— Budget neutralize the averaged relative weights.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).

To achieve budget neutrality under the requirement at § 412.517(b), under our established methodology, for each annual update the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, as we proposed, we continued to apply budget neutrality adjustments in determining the FY 2023 MS–LTC–DRG relative weights so that our update the MS–LTC–DRG classifications and relative weights for FY 2023 are made in a budget neutral manner. In addition, as discussed in section VIII.B.3.b. of the preamble to this final rule, we are finalizing our proposal that the 10-percent cap on the reduction in a MS–LTC–DRG's relative weight in a given year be budget neutral. Therefore, for FY 2023, we are applying two budget neutrality factors to determine the MS–LTC–DRG relative weights. In this step, we describe the determination of the budget neutrality adjustment that accounts for the update of the MS–LTC–DRG classifications and relative weights prior to the application of the 10-percent cap. In steps 12 and 13, we describe the application of the 10-percent cap policy (step 12) and the determination of the budget neutrality factor that accounts for the application of the 10-percent cap policy (step 13).

As described previously, the relative weights constructed up to this point in our methodology were calculated based on two different set of claims (the applicable LTCH cases that included COVID–19 cases and the applicable LTCH cases that excluded COVID–19 cases) and then averaged together. However, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28475), when modeling payments for determining the budget neutrality factors, we proposed to use the set of LTCH cases that include COVID–19 cases. In the absence of a set of MedPAR claims that reflect our expectation that there will be fewer (but not zero) COVID–19 cases in FY 2023 as compared to the COVID–19 cases in the FY 2021 claims data, we stated our belief that this is the best data available for determining the budget neutrality factors. We solicited feedback from commenters on alternative ways to use the FY 2021 claims data for purposes of calculating the FY 2023 budget neutrality factors. We received no comments on this proposal and are finalizing this proposal without modification. Therefore, for this final rule, when modeling payments for determining the budget neutrality factors we used the set of LTCH cases that include COVID–19 cases.

In this final rule, to ensure budget neutrality for the update to the MS–LTC–DRG classifications and relative weights prior to the application of the 10-percent cap (that is, uncapped relative weights), under § 412.517(b), we continued to use our established two-step budget neutrality methodology. Therefore, in the first step of our MS–LTC–DRG update budget neutrality methodology, for FY 2023, we calculated and applied a normalization factor to the recalibrated relative weights (the result of Steps 1 through 10 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the normalization factor for FY 2023, we used the following three steps: (1.a.) use the applicable LTCH cases from the best available data (that is, LTCH discharges from the FY 2021 MedPAR file, including the COVID–19 cases as discussed previously) and group them using the FY 2023 GROUPER (that is, Version 40 for FY 2023) and the recalibrated FY 2023 MS–LTC–DRG uncapped relative weights (determined in Steps 1 through 10 discussed previously) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2022 GROUPER (Version 39) and FY 2022 MS–LTC–DRG relative weights and calculate the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average case-mix index for FY 2022 (determined in Step 1.b.) by the average

case-mix index for FY 2023 (determined in Step 1.a.). As a result, in determining the MS–LTC–DRG relative weights for FY 2023, each recalibrated MS–LTC–DRG uncapped relative weight was multiplied by the normalization factor of 0.99884 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produces ''normalized relative weights.''

In the second step of our MS–LTC–DRG update budget neutrality methodology, we calculated a budget neutrality adjustment factor consisting of the ratio of estimated aggregate FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.b. stated previously) before reclassification and recalibration to estimated aggregate payments for FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases after reclassification and recalibration (that is, the sum of all calculations under Step 1.a. stated previously).

That is, for this final rule, for FY 2023, we determined the budget neutrality adjustment factor using the following three steps: (2.a.) simulate estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped normalized relative weights for FY 2023 and GROUPER Version 40 (as described previously); (2.b.) simulate estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2022 GROUPER (Version 39) and the FY 2022 MS–LTC–DRG relative weights in Table 11 of the FY 2022 IPPS/LTCH PPS final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the FY 2023 MS–LTC–DRG relative weights, each uncapped normalized relative weight was then multiplied by a budget neutrality factor of 0.9937739 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology.

Step 12—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights.

As discussed in section VIII.B.3.b. of the preamble to this final rule, we are establishing a 10-percent cap on the reduction in a MS–LTC–DRG's relative weight in a given year, beginning in FY 2023. Specifically, in cases where the relative weight for a MS–LTC–DRG would decrease by more than 10-percent in a given year, we are limiting the reduction to 10-percent for that year. Under this provision, this 10-percent cap will only be applied to the relative weights for MS–LTC–DRGs with 25 or more applicable LTCH cases and will not be applied to the low-volume MS–LTC–DRGs identified in Step 3 or the no-volume MS–LTC–DRGs identified in Step 8. Therefore, in this step, for each FY 2023 MS–LTC–DRG with 25 or more applicable LTCH cases (excludes low-volume and zero-volume MS–LTC–DRGs) we compared its FY 2023 relative weight (after application of the normalization and budget neutrality factors determined in Step 11), to its FY 2022 MS–LTC–DRG relative weight. For any MS–LTC–DRG where the FY 2023 relative weight would otherwise have declined more than 10 percent, we established a capped FY 2023 MS–LTC–DRG relative weight that would be equal to 90 percent of that MS–LTC–DRG's FY 2022 relative weight (that is, we set the FY 2023 relative weight equal to the FY 2022 weight $\times$ 0.90).

Step 13—Calculate the MS–LTC–DRG cap budget neutrality factor.

As discussed in section VIII.B.3.b. of the preamble to this final rule, we also are applying a budget neutrality adjustment to the MS–LTC–DRG relative weights so that the 10-percent cap on relative weight reductions is implemented in a budget neutral manner. Therefore, we are determining the budget neutrality adjustment factor for our 10-percent cap on relative weight reductions using the following three steps: (a) simulate estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the capped relative weights for FY 2023 (determined in Step 12) and GROUPER Version 40; (b) simulate estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped relative weights for FY 2023 (determined in Step 11) and GROUPER Version 40; and (c) calculate the ratio of these estimated total payments by dividing the value determined in step (b) by the value determined in step (a). In determining the FY 2023 MS–LTC–DRG relative weights, each capped relative weight was then multiplied by a budget neutrality factor of 0.998734 (the value determined in step (c)) to achieve the budget neutrality requirement.

Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2023. We also are making available on our website the two sets of relative weights that were averaged together in determining the FY 2023 MS–LTC–DRG relative weights. That is, the set of relative weights based on applicable LTCH cases that included COVID–19 cases and the set of relative weights based on applicable LTCH cases that excluded COVID–19 cases. We also are making available on the website the MS–LTC–DRG relative weights prior to the application of the 10-percent cap on MS–LTC–DRG relative weight reductions and corresponding cap budget neutrality factor.

C. Changes to the LTCH PPS Payment Rates and Other Changes to the LTCH PPS for FY 2023

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section of the final rule, we discuss the factors that we used to update the LTCH PPS standard Federal payment rate for FY 2023, that is, effective for LTCH discharges occurring on or after October 1, 2022 through September 30, 2023. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at 42 CFR 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate from FYs 2003 through 2015, and LTCH PPS standard Federal payment rate from FY 2016 through present, as implemented under 42 CFR 412.523(c)(3), we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2023 IPPS/LTCH PPS final rule, we present our policies related to the annual update to the LTCH PPS

standard Federal payment rate for FY 2023.

The update to the LTCH PPS standard Federal payment rate for FY 2023 is presented in section V.A. of the Addendum to this final rule. The components of the annual update to the LTCH PPS standard Federal payment rate for FY 2023 are discussed in this section of the final rule, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2023 as required by the statute (as discussed in section VIII.C.2.c. of the preamble of this final rule). As we proposed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28476), we also made an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2023 on estimated aggregate LTCH PPS payments, in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B. of the Addendum to this final rule).

2. FY 2023 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021 (85 FR 58907 through 58909). For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2023

As previously noted, we adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021. The 2017-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. (For additional details on the development of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).) We continue to believe that the 2017-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2021 IPPS/LTCH PPS final rule. Therefore, in this final rule, as we proposed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28476), we used the 2017-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2023.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A), as applicable. Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by ''the productivity adjustment'' described in section 1886(b)(3)(B)(xi)(II) of the Act. Clause (ii) of section 1886(m)(3)(A) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act; therefore, it is not applicable for FY 2023.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage points reduction to any update under 42 CFR 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (42 CFR 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at 42 CFR 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this final rule.)

d. Annual Market Basket Update Under the LTCH PPS for FY 2023

Consistent with our historical practice, we estimate the market basket increase and the productivity adjustment based on IGI's forecast using more recent available data. Based on IGI's fourth quarter 2021 forecast, the proposed FY 2023 market basket update for the LTCH PPS using the 2017-based LTCH market basket was 3.1 percent. The proposed productivity adjustment for FY 2023 based on IGI's fourth quarter 2021 forecast was 0.4 percent.

For FY 2023, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we proposed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28477), to reduce the FY 2023 market basket increase by the FY 2023 productivity adjustment. To determine the proposed market basket increase for LTCHs for FY 2023, as reduced by the proposed productivity adjustment, consistent with our established methodology, we subtracted the proposed FY 2023 productivity adjustment from the FY 2023 market basket increase. (For additional details on our established methodology for adjusting the market basket increase by the productivity adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2023, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, the proposed 3.1 percent market basket update to the LTCH PPS standard Federal payment rate for FY 2023 would be reduced by the 0.4 percentage point productivity adjustment as required under section 1886(m)(3)(A)(i) of the Act and by the additional 2.0 percentage points reduction required by section 1886(m)(5) of the Act.

In the FY 2023 IPPS/LTCH PPS proposed rule, in accordance with the statute, we proposed to reduce the proposed FY 2023 market basket update of 3.1 percent (based on IGI's fourth quarter 2021 forecast of the 2017-based LTCH market basket) by the proposed FY 2023 productivity adjustment of 0.4 percentage point (based on IGI's fourth quarter 2021 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we proposed to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2023 of 2.7 percent (that is, more recent estimate of the LTCH PPS market basket increase of 3.1 percent less the productivity adjustment of 0.4 percentage point). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), we proposed to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we proposed to establish an annual update to the LTCH PPS standard Federal payment rate of 0.7 percent (that is, 2.7 percent minus 2.0 percentage points) for FY 2023 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, we proposed in the FY 2023 IPPS/LTCH PPS proposed rule (86 FR 28477) to use a more recent estimate of the market basket and the productivity adjustment, if appropriate, in the final rule to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2023. We note that, consistent with historical practice, we also proposed to adjust the FY 2023 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to the proposed rule).

Comment: A number of commenters expressed concern that the proposed 2017-based LTCH market basket growth rate of 3.1 percent was inadequate and did not reflect current inflationary trends. These commenters cited several reasons why they believe the proposed market basket was underestimated, including significant rises in hospital labor costs (especially contract nursing costs), as well as rises in other hospital costs (such as equipment and supplies). Several commenters cited recent growth in the Bureau of Labor Statistics (BLS) Consumer Price Index (CPI) as evidence of the inflationary pressures inflicted upon hospitals.

Several commenters expressed that, since the market basket is a time-lagged estimate that uses historical data to forecast into the future, it is most suitable for forecasting changes in a steady-state economy with small and stable changes in inflation and costs. However, these commenters believe the current inflationary environment is not a typical economic environment and therefore the resulting market basket estimates are inadequate. A commenter stated that the construction of the market basket itself does not allow it to fully capture unexpected shocks because it is a time-lagged rolling average estimate.

Commenters requested CMS to ensure that the market basket and update factor reflect the actual experiences of LTCHs and be modified accordingly. Several commenters urged CMS to identify more accurate and up-to-date data inputs to calculate a market basket update that better represents the inflationary pressures that hospitals are facing.

Response: CMS has historically used a market basket to account for input price increases in the services furnished by fee-for-service providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021 (85 FR 58907 through 58909). We believe the 2017-based LTCH market basket increase adequately reflects the average change in the price of goods and services hospitals purchase in order to provide LTCH medical services, and is appropriate to use as the market basket percentage increase. As described in the FY 2021 final rule (86 FR 45194 through 45213), the LTCH market basket is a fixed-weight, Laspeyres-type index that measures price changes over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services. As such, the LTCH market basket increase would reflect the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage price growth or higher energy prices), but would inherently not reflect other factors that might increase the level of costs, such as the quantity of labor used or any shifts between contract and staff nurses. We note that cost changes (that is, the product of price and quantities) would only be captured in the market basket weights when the index is rebased and the base year is updated to a more recent time period. Comments requesting that CMS rebase the LTCH market basket and our response are discussed later in this section.

We agree with the commenters that recent higher inflationary trends have impacted the outlook for price growth over the next several quarters. At the time of the FY 2023 IPPS/LTCH proposed rule, based on IGI's fourth quarter 2021 forecast with historical data through the third quarter of 2021, IGI forecasted the 2017-based LTCH market basket update of 3.1 percent for FY 2023 reflecting forecasted compensation prices of 3.9 percent (by comparison, compensation price growth in the 2017-based LTCH market basket averaged 2.1 percent from 2012–2021). In the FY 2023 IPPS/LTCH proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2023 LTCH market basket

update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy (including the more recent historical CPI growth, impacts of the Russia/Ukraine war, current expectations regarding changes to Federal Reserve interest rates, and tight labor markets). Based on IGI's second quarter 2022 forecast with historical data through the first quarter of 2022, we are projecting a FY 2023 LTCH market basket update of 4.1 percent (reflecting forecasted compensation price growth of 4.8 percent) and productivity adjustment of 0.3 percentage point. Therefore, for FY 2023, we are finalizing an LTCH update of 3.8 percent (4.1 percent less 0.3 percentage point), compared to 2.7 percent that we had proposed. We note that the final FY 2023 LTCH market basket growth rate of 4.1 percent would be the highest market basket update implemented in an IPPS/LTCH final rule going back to RY 2004.

Comment: Some commenters maintained that, in consideration of rapidly increasing labor costs, it would be appropriate for CMS to implement a temporary payment adjustment increase or add-on payment to LTCH payments for FY 2023. The commenters stated their belief that CMS has the authority to determine appropriate adjustments to the LTCH PPS under section 123 of the BBRA as amended by section 307(b)(1) of the BIPA. A commenter requested that such a payment adjustment continue to be applied until CMS rebases the LTCH PPS market basket.

Response: We disagree with the commenters that CMS should apply a temporary payment adjustment or add-on payment to the LTCH PPS to account for the increases in labor costs at LTCHs that they believe were not being captured in the market basket. As discussed earlier, we believe the LTCH market basket increase appropriately reflects the input price growth (including compensation price growth) that LTCHs incur in providing medical services. As also described earlier, we are using an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy (including the more recent historical CPI growth, impacts of the Russia/Ukraine war, current expectations regarding changes to Federal Reserve interest rates, and tight labor markets). As a result, the update for FY 2023 of 3.8 percent is 1.1 percentage points higher than the proposed update of 2.7 percent.

Comment: Several commenters requested that CMS apply a retrospective payment adjustment that accounts for the difference between the 2.6 percent market basket increase that was implemented in FY 2022 and what the market basket is currently projected to be for FY 2022. Several commenters stated that the FY 2022 market basket increase that was used to determine the annual update did not capture significant increases in labor expenses that occurred in FY 2022.

Response: Under the law, the LTCH PPS is a per-discharge prospective payment system that uses a market basket increase to set the annual update prospectively. This means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. For instance, the 2017-based LTCH market basket growth rate for FY 2023 in this final rule is based on IGI's second quarter 2022 forecast with historical data through the first quarter of 2022. While there is currently no mechanism to adjust for market basket forecast error in the LTCH payment update, the forecast error for a market basket update is equal to the actual market basket increase for a given year less the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. We note that FY 2022 historical data are not yet available to calculate a forecast error for FY 2022. For this final rule, we have incorporated more recent historical data and forecasts to capture the price and wage pressures facing LTCHs and believe the market basket increase that we are finalizing is the best available projection of inflation to determine the applicable percentage increase for the LTCH payments in FY 2023. For these reasons we are not adopting the commenters' suggestion to adjust for the difference between the currently projected market basket increase for FY 2022 and the forecasted market basket increase used in determining the FY 2022 update.

Comment: We received numerous comments about our proposed productivity adjustment to the FY 2023 LTCH market basket update. Commenters generally stated that a negative productivity adjustment is inappropriate because evidence suggests that productivity for LTCHs has decreased, rather than increased over the past year. Commenters requested CMS to use its existing statutory authority to remove the productivity adjustment for FY 2023. A commenter requested that we remove the productivity adjustment for FY 2023, and any fiscal year during which the PHE for COVID–19 was in effect.

A subset of these commenters also requested that CMS reconsider the appropriateness of the productivity adjustment to LTCHs more broadly. They stated that the productivity adjustment, based on a 10-year moving average of changes in the annual economy-wide private nonfarm business total factor productivity, is not representative of the cost structure of LTCHs. These commenters expressed concern that hospital work is extremely dependent on human capital and that increased operational efficiencies are relatively limited for LTCHs compared with industries that are able to produce greater efficiencies through automation. Commenters specifically cited evidence for why they believe it is unrealistic for hospitals to achieve the same productivity gains as the private nonfarm business sector in FY 2023. For example, a commenter cited the significant decrease in hospital employment levels that have occurred during the pandemic and the resulting reliance on contract staffing firms to address staffing shortages as a reason why they believe hospitals are experiencing declines in productivity during the pandemic.

Response: Section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment, described in section 1886(b)(3)(B)(xi) of the Act; therefore, we do not have the authority to eliminate the productivity adjustment. In section V.A.1. of this preamble, in response to similar comments, we explained that we do not believe it is appropriate to eliminate the productivity adjustment for FY 2023 in this final rule. In that same section, we discuss the methodology for calculating and applying the productivity adjustment required by section 1886(b)(3)(B)(xi) of the Act that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692). As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) and BLS publishes the official measures of private nonfarm business productivity for the U.S. economy. (We note, beginning with the November 18,

2021 release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP), and beginning with the FY 2022 IPPS/LTCH PPS final rule, we refer to this adjustment as the productivity adjustment rather than the MFP adjustment. The adjustment continues to rely on the same underlying data and methodology.)

For the FY 2023 IPPS/LTCH proposed rule, based on IGI's fourth quarter 2021 forecast, the productivity adjustment was projected to be 0.4 percentage point for FY 2023. For this final rule, based on IGI's second quarter 2022 forecast, we are updating the productivity adjustment to reflect more recent historical data as published by BLS as well as a revised economic outlook for FY 2022 and FY 2023. Using this more recent forecast, the FY 2023 productivity adjustment based on the 10-year moving average growth in economy-wide total factor productivity for the period ending FY 2023 is 0.3 percent.

Comment: Several commenters requested that CMS rebase and revise the 2017-based LTCH market basket for FY 2023 using the most recent LTCH data on labor costs in order for the FY 2023 market basket estimate to accurately reflect recent inflationary trends. A commenter stated that the unprecedented COVID–19 pandemic has drastically changed hospital operations and the costs associated with operating a hospital. This commenter also stated its view that the market basket update that CMS applies each year is simply unable to account for many of the changes to hospital operations and costs since the pandemic.

Response: As described previously, the LTCH market basket measures price changes (including changes in the prices for wages and salaries) over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services until the market basket is rebased. The LTCH market basket was last rebased in the FY 2021 IPPS/LTCH PPS final rule using 2017 Medicare cost reports (85 FR 58909 through 58926), the most recent year of complete data available at the time of the rebasing. We note that we did not propose to rebase the LTCH market basket in the FY 2023 IPPS/LTCH proposed rule; however, we did review the most recent Medicare cost report data available for LTCHs submitted as of March 2022, which includes data for 2018–2020. The Medicare cost report data showed that between 2017 and 2019 the compensation cost weight (which reflects expenses for wages and salaries, employee benefits, and contract labor) was relatively unchanged, decreasing by roughly 1.2 percentage points relative to the 2017-based LTCH market basket compensation cost weight. We note that data through 2021 are incomplete at this time and therefore, we are not able to estimate a compensation cost share weight for 2021 at this time. We have concluded that based on this preliminary analysis it is unclear whether these trends through 2020 are reflective of sustained shifts in the cost structure for long-term care hospitals or whether they were temporary as a result of the COVID–19 PHE. Therefore, we believe it is premature at this time to use more recent Medicare cost report data to derive a rebased and revised LTCH market basket. We will continue to monitor these data and any changes to the LTCH market basket will be proposed in future rulemaking.

Comment: A few commenters expressed concern that the 2023 rate increase CMS finalized for Medicare Advantage plans was significantly higher than the proposed FY 2023 update for LTCH PPS payments. These commenters believe this difference supports their view that the proposed FY 2023 update for LTCH PPS payments was inadequate.

Response: As stated previously, the Medicare program has historically used a market basket to account for input price increases in the services furnished by fee-for-service providers; in most instances, basing these updates on input price indexes is statutorily required. For the LTCH PPS we adopted a similar approach of using a market basket to update PPS payments, and beginning in FY 2021 this update reflected the percentage change in the 2017-based LTCH market basket (85 FR 58907 through 58909). For this FY 2023 IPPS/LTCH final rule, based on a more recent forecast than was used for the proposed rule, the LTCH market basket increase is 4.1 percent (one percentage point higher than the estimated market basket increase published in the FY 2023 IPPS/LTCH proposed rule).

After consideration of public comments, we are finalizing the LTCH payment update using more recent forecast of the market basket and productivity adjustment. As such, based on IGI's second quarter 2022 forecast, the FY 2023 market basket update for the LTCH PPS using the 2017-based LTCH market basket is 4.1 percent. The current estimate of the productivity adjustment for FY 2023 based on IGI's second quarter 2022 forecast is 0.3 percent. Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we are establishing an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2023 of 3.8 percent (that is, more recent estimate of the LTCH PPS market basket increase of 4.1 percent less the productivity adjustment of 0.3 percentage point).

For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), as we proposed, we further reduced the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1.8 percent (that is, 3.8 percent minus 2.0 percentage points) for FY 2023 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP.

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

In section IX. of the preamble of the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28477 through 28612), we sought public comment on the following focus areas and proposed changes to the Medicare quality reporting programs:

- In section IX.A., assessment of the impact of climate change and health equity.
- In section IX.B., overarching principles in measuring healthcare quality disparities in hospital quality programs.
- In section IX.C., advancement of digital quality measurement and use of Fast Healthcare Interoperability Resources (FHIR) in hospital quality programs.
- In section IX.D., advancing the Trusted Exchange Framework and Common Agreement (TEFCA).
- In section IX.E., the Hospital IQR.
- In section IX.F., the PCHQR Program.
- In section IX.G., the LTCH QRP.
- In section IX.H. the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (previously known as the Medicare EHR Incentive Program).

A. Current Assessment of Climate Change Impacts on Outcomes, Care, and Health Equity—Request for Information

1. Background

A recent consensus statement signed by more than 200 medical journals

noted climate change represents the greatest threat to global public health of the coming century.[327] Pollution associated with the burning of fossil fuels is known to cause serious harm and loss in productivity, and resultant climate instability introduces a combination of catastrophic weather events and chronic disease impacts that create serious burdens on organizations providing health care.[328] There is also evidence that climate change disproportionately harms underserved populations (for example, racial and ethnic minority groups, indigenous people, members of religious minorities, people with disabilities, sexual and gender minorities, individuals with limited English proficiency, older adults, and rural populations).[329] Long-term discrimination and disparities based on social determinants of health mean that these groups are often less equipped to withstand climate threats and are more susceptible to associated harm.[330] For example, Black Americans are much likelier to experience premature mortality as a result of extreme heat, and childhood asthma rates related to warming temperatures will be much higher in minority communities, as well.[331] Out of concern for the health of individuals, and to maintain uninterrupted operations in service of patients, we believe the healthcare sector more fully explore how to effectively prepare for climate threats. Because healthcare facilities also emit greenhouse gases (GHGs) that contribute to climate change and its impacts, we believe that they study how best to reduce those emissions, as well.

2. Solicitation of Comments on the Current State of Health System Climate Change Efforts

In the Request for Information (RFI) in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28478 through 28479), we sought comment on how hospitals, nursing homes, hospices, home health agencies, and other providers can better prepare for the harmful impacts of climate change on their patients, and how we can support them in doing so. Because research has shown that climate change causes harm to individuals (through both catastrophic events and chronic disease)[332] and because there is evidence to show that climate change will disproportionately harm underserved populations,[333] we believe that it is critical to study and prepare for these impacts.

Generally, we sought input on what the U.S. Department of Health and Human Services (HHS) and CMS can do to support hospitals, nursing homes, hospices, home health agencies, and other providers in more effectively: (a) Determining likely climate impacts (that is, both immediate impacts associated with climate-related disasters and long-term chronic disease implications of climate change) on their patients, residents and consumers so that they can develop plans to mitigate those impacts; (b) understanding exceptional threats that climate-related emergencies (for example., storms, floods, extreme heat, wildfires) present to continuous facility operations (including potential disruptions in patient services associated with catastrophic events as a result of power loss, limited transportation, evacuation challenges, etc.) so they can better address those; and (c) understanding how to take action on reducing their emissions and tracking their progress in this regard. We believe this will inform the development and updating of policies that can assist providers in responding to climate-related challenges (for example, policies related to emergency preparedness) as well as the updating of HHS climate-health tools and resources.

We also invited public comments on the following topics (understanding that some provider types might have done more work in this area than others):

- The availability of information, such as analyses of climate change impacts (whether developed internally or collected from outside sources), that hospitals, nursing homes, hospices, home health agencies, and other providers can access to better understand climate threats to their patients, community, and staff.
- The degree to which different provider types currently complete comprehensive climate change risk assessments to better understand risks to their patient populations and the costs incurred due to catastrophic climate events and climate-related chronic disease.
- The degree to which facility efforts to prepare for climate impacts overlap with the work they already complete to meet CMS's Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, and the degree to which related CMS requirements sufficiently (or insufficiently) prepare them for the threats created by climate change and help or hinder these efforts.
- The degree to which hospitals, nursing homes, hospices, home health agencies, and other providers measure and share performance associated with their response to climate-related catastrophes (for example, measuring harm to vulnerable populations as a result of such events, or extent of disruption in service).
- The nature of facility plans for assisting the community and patients to prepare for and recover from climate-related events, as well as the nature of plans for evacuating patients with differing needs, including those with disabilities.
- The degree to which climate change, and climate change linked to health equity, is publicly addressed in strategic plans and objectives in your facility or system, and the degree to which hospital leadership regularly reviews progress on goals related to climate preparedness and mitigation and invests in health professional training on this topic.
- Whether health systems and facilities have time-bound, public aims for GHG emissions reduction, and, if yes, whether those aims relate to direct facility emissions, emissions associated with purchased energy, emissions associated with supply chain or some combination of these.
- The measures that health systems and facilities use to track their progress on GHG emissions reduction and use of renewable energy, as well as the data collection tools that they may use support this tracking.
- The tools and supports that health systems and facilities most heavily rely on to support their efforts to reduce GHG emissions.
- How HHS and CMS can support hospitals, nursing homes, hospices, home health agencies, and other providers in their efforts to more fully prepare for climate change's catastrophic and chronic impacts on

[327] Atwoli, L., Banqui A., Benfield T., et al. (2021). Call for emergency action to limit global temperature increases, restore biodiversity, and protect health. Lancet, 398(10304):939–41.

[328] Eckelman, M., Huang K., et al. (2020). Health Care Pollution and Public Health Damage in the United States: An Update. Health Affairs, 39:12.

[329] U.S. Environmental Protection Agency. (2021). Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency, EPA 430–R–21–003.

[330] U.S. Environmental Protection Agency. (2021). Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency, EPA 430–R–21–003.

[331] U.S. Environmental Protection Agency. (2021). Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency, EPA 430–R–21–003.

[332] Eckelman, M., Huang K., et al. (2020). Health Care Pollution and Public Health Damage in the United States: An Update. Health Affairs, 39:12.

[333] U.S. Environmental Protection Agency. (2021). Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency, EPA 430–R–21–003.

their operations and the people they serve, as well as what incentives (for example, recognition, payment, reporting) might assist them in taking more action on climate readiness and emissions reduction.

- Whether accrediting organizations assess facilities' readiness for climate-related threats and their efforts to reduce GHG emissions.

We received comments on these topics.

Comment: We received many comments expressing support for this request for information on health impacts due to climate change and how we could potentially support hospitals, nursing homes, hospices, home health agencies, and other providers to more effectively determine and plan for climate impacts. Many commenters underscored the impacts of climate change, particularly on specific disease and services lines, as well as on underserved populations. Many commenters provided sources of public data and analyses that depict healthcare's impact on climate. Many commenters also identified pledges to which they committed in pursuit of reducing their climate impact.

The vast majority of commenters suggested that we incentivize and provide funding for participation in climate change initiatives. Several commenters proposed a value-based purchasing program as a potential format for such participation. A commenter suggested projects that reduce climate footprint could count towards community benefit.

Many commenters provided feedback and insights regarding how we can assess the impact of climate change on patients. Many commenters recommended undertaking additional analysis as the first step towards helping the healthcare industry understand and impact climate change. A commenter recommended hospitals study their internal patient level data to identify climate impacts on patients. A few commenters also recommended updating screening tools to include climate change health impact topics.

Commenters identified many initiatives and projects they are pursuing to reduce their footprint. Commenters recommended that we develop a repository of data and projects that have addressed climate change; highlight the impact of single use products versus reprocessing medical equipment and forced device obsolescence; encourage the reduction and recycling of anesthesia gases; leverage lessons learned from the reduction of highly enriched uranium; understand data storage and its impact on the environment; update aging healthcare infrastructure and building codes, especially on temperature regulation requirements; update guidance for on-site alternative energy sources and micro-grids; and add education on climate topics for clinicians. Many commenters also identified the need to update hospital emergency preparedness plans to include responses to climate-related disasters, including short-term, long-term, and post-disaster responses.

Commenters emphasized that climate change is not just a hospital issue. They recommended the that we engage with relevant groups including suppliers, advocacy groups, and other government agencies. A few commenters suggested that we work with interested parties to perform a life cycle analysis to identify high emission, low value clinical devices or services. A few commenters suggested that we continue to consider, and perhaps expand, the definition of climate change.

A few commenters cautioned us about considering new initiatives against the backdrop of the challenges stemming from the COVID–19 pandemic. A commenter specifically encouraged us to ensure that our work on addressing climate change does not detract from the mission of improving health. A commenter shared that climate related initiatives are funded through tax-exemption, which is not available to non-profit healthcare entities. Furthermore, A commenter questioned whether HHS has the authority to impose climate-change requirements. Finally, a commenter advised that any expansion of emergency preparedness requirements be non-burdensome.

In summary, the organizations and individuals that submitted comments almost uniformly embraced the importance of setting goals for reduced emissions and increased climate resilience but also repeatedly requested the following:

- More timely data to understand threats and health impacts associated with climate change, especially for vulnerable and marginalized populations, as well as information on cost impacts for care providers.
- Financing supports and incentives to help deepen their work in this area (with attention to the needs of different provider types).
- Technical assistance tools to assist operational and clinical improvements in this area (with attention to frontline specialties whose work intersects with climate health).
- Standardized measures and measurement frameworks to help with progress tracking and reporting (with mixed views on whether such reporting be mandatory or voluntary).
- Updates to/simplification of emergency preparedness requirements, conditions of participation and other regulations to help all provider and supplier types to be more responsive to climate-related challenges.
- Attention to the challenges different provider types, already under strain from the pandemic, must address to take on this work and ensure no compromise in the quality of care delivery.
- Attention to the importance of engaging supply chain stakeholders in order to fully address the challenge of reducing emissions.

Response: We thank the commenters for their input, recommendations, and many ideas. We will consider all the feedback received as we continue to understand how hospitals, nursing homes, hospices, home health agencies, and other providers can better prepare for the harmful impacts of climate change on their patients, and how we can support them in doing so. We additionally appreciate the many commenters who would like to volunteer to be a part of groups to help develop any future policies on this topic. We will continue to engage all interested parties via multiple avenues including future notice-and-comment rulemaking.

B. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—Request for Information

1. Background

Significant and persistent inequities in healthcare outcomes exist in the United States (U.S.). Belonging to a racial or ethnic minority group; being a member of a religious minority; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level, are often associated with worse health outcomes.[334] [335] [336] [337] [338] [339] [340] [341] [342] [343] We are committed to achieving equity in healthcare outcomes for our beneficiaries by supporting healthcare providers' quality improvement activities to reduce health disparities, enabling beneficiaries to make more informed decisions, and promoting healthcare provider accountability for healthcare disparities.[344]

Health equity is an important component of an equitable society. Equity, as defined in Executive Order 13985, is ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQ+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [345] We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, religion, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[346]

Advancing health equity will require a variety of efforts across the healthcare system. The reduction in healthcare disparities is one aspect of improving equity that we have prioritized. In a RFI that we included in the FY 2022 IPPS/LTCH PPS final rule, titled ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' (86 FR 45349 through 45360), we described programs and policies we have implemented over the past decade with the aim of identifying and reducing healthcare disparities, including: the CMS Mapping Medicare Disparities Tool [347] and the CMS Disparity Methods stratified reporting.[348] CMS has also supported HHS' efforts to implement the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (78 FR 58539); [349] as well as improvement of the collection of drivers of health in standardized patient assessment data in four post-acute care settings and the collection of health-related social need data by model participants in the Accountable Health Communities Model.[350] [351] [352]

Measuring healthcare disparities and reporting these results to healthcare providers is a cornerstone of our approach to advancing healthcare equity. It is important to consistently measure differences in care received by different groups of our beneficiaries, and this can be achieved by methods to stratify quality measures. Measure stratification is defined for this purpose as calculating measure results for specific groups or subpopulations of patients. Assessing healthcare disparities through stratification is only one method for using healthcare quality measurement to address health equity, but it is an important approach that allows healthcare providers to tailor quality improvement initiatives, decrease disparity, track improvement over time, and identify opportunities to evaluate upstream drivers of health. The use of measure stratification to assess disparities has been identified by our Office of Minority Health as a critical component of an organized response to health disparities.[353] To date, we have

[334] Joynt KE, Orav E, Jha AK. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7): 675–681.

[335] Vu M. et al. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6). doi: 10.1089/jwh.2015.5517.

[336] Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016) The Association between Discrimination and the Health of Sikh Asian Indians. Health Psychology, 35(4), 351–355. *https://doi.org/10.1037/hea0000268*.

[337] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and thirty-day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. British Medical Journal, 346.

[338] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. New England Journal of Medicine, 371(24): 2298–2308.

[339] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs, 40(2): 307–316.

[340] Rural Health Research Gateway. (2018). Rural communities: age, income, and health status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf*.

[341] HHS Office of Minority Health. (2020). Progress Report to Congress: 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Available at: *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=57*.

[342] Heslin, KC, Hall, JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep 2021;70:149–154. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm*.

[343] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. preprint. medRxiv. 2020;2020.07.21. 20159327. doi:10.1101/2020.07.21.20159327. Available at: *https://pubmed.ncbi.nlm.nih.gov/32743608/*.

[344] Centers for Medicare and Medicaid Services. (2016). CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf*.

[345] **Federal Register**. (2021). Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Available at: *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*.

[346] Centers for Medicare & Medicaid Services. (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity*.

[347] Centers for Medicare and Medicaid Services. (2021). CMS Office of Minority Health. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities*.

[348] Centers for Medicare and Medicaid Services. Disparity Methods Confidential Reporting. Available at: *https://qualitynet.cms.gov/inpatient/measures/disparity-methods*.

[349] **Federal Register**. (2013). National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care. Available at: *https://www.federalregister.gov/documents/2013/09/24/2013-23164/national-standards-for-culturally-and-linguistically-appropriate-services-clas-in-health-and-health*.

[350] Centers for Medicare and Medicaid Services. (2021). Accountable Health Communities Model. Available at: *https://innovation.cms.gov/innovation-models/ahcm*.

[351] Centers for Medicare and Medicaid Services. The Accountable Health Communities Health-Related Social Needs Screening Tool. Available at: *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf*.

[352] Centers for Medicare and Medicaid Services. (2021). IMPACT Act Standardized Patient Assessment Data Elements. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/-IMPACT-Act-Standardized-Patient-Assessment-Data-Elements*.

[353] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to

Continued

performed analyses of disparities in our quality programs by using a series of stratification methodologies identifying quality of care for patients with heightened social risk or with demographic characteristics with associations to poorer outcomes. In 2015, we began providing entity-level quality and member experience data to all Medicare Part C/D health plans stratified by race and ethnicity. In 2018, we introduced confidential reporting of hospital quality measure data stratified by dual eligibility in the Hospital IQR Program (81 FR 25199; 82 FR 38403 through 38409).[354]

We are continuing to evaluate opportunities to expand our measure stratification reporting initiatives using existing sources of data. Our goal is to provide comprehensive and actionable information on health disparities to healthcare providers participating in our quality programs to support quality improvement efforts. We are doing this, in part, by starting with confidential reporting of stratified measure results that highlight potential gaps in care between groups of patients. This includes examining the possibility of reporting disparities in care based on additional social risk factors and demographic variables associated with historic disadvantage in the healthcare system, and examining disparities through the use of stratified healthcare quality measures across a variety of care settings. As we consider expanding our disparity measurement initiatives through the use of measure stratification, we believe that we model these efforts on existing best practices, such as considering feedback and making use of lessons learned through the development of our existing disparity reporting efforts.

There are several key elements that we intend to take into account as we consider advancing the use of measurement and stratification as tools to address healthcare disparities and advance healthcare equity. In the FY 2023 IPPS/LTCH PPS proposed rule, we sought input on key considerations in five specific areas that could inform our approach (87 FR 28479 through 28486). Each is described in more detail later in this section:

- *Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Programs*—This section identifies potential approaches for measuring healthcare disparities through measure stratification in CMS quality reporting programs.
- *Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting Across CMS Quality Reporting Programs*—This section describes considerations that could inform the selection of healthcare quality measures to prioritize for stratification.
- *Principles for Social Risk Factor and Demographic Data Selection and Use*—This section describes several types of social risk factor and demographic data that could be used in stratifying measures for healthcare disparity measurement.
- *Identification of Meaningful Performance Differences*—This section reviews several strategies for identifying meaningful differences in performance when measure results are stratified.
- *Guiding Principles for Reporting Disparity Results*—This section reviews considerations we could take into account in determining how quality programs will report measure results stratified by social risk factors and demographic variables to healthcare providers, as well as the ways different reporting strategies could hold healthcare providers accountable for identified disparities.

2. Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Programs

One of our goals in developing methods to measure disparities in care for beneficiaries is to provide actionable and useful results to healthcare providers. By quantifying healthcare disparities (for example, through quality measure stratification), we aim to provide useful tools for healthcare providers to drive improvements. We hope that these results support healthcare provider efforts to examine the underlying drivers of disparities in their patients' care and to develop their own innovative and targeted quality improvement interventions. With stratified disparity information available, it may be possible to drive system-wide advancement through incremental, provider-level improvement.

There are multiple conceptual approaches to stratifying measures. Since 2018, we have focused on illuminating healthcare disparities by reporting stratified results of existing quality measures by dual eligible status in two complementary ways.[355] First, after stratification by dual eligible status, measure results for subgroups of patients served by an individual healthcare provider can be directly compared. This type of comparison identifies such disparities, or gaps in care or outcomes between groups at a hospital. This approach is sometimes referred to as ''within-provider'' disparity and can be done for most measures that include patient-level data for most care settings. ''Within-provider'' disparities are a helpful means by which to quantitatively express disparities in care at the provider level.[356] Second, a healthcare provider's performance on a measure for only dual eligible patients is compared to other healthcare providers' performance for that same subgroup of patients (sometimes referred to as ''across-provider'' disparities measurement). This type of comparison illuminates the healthcare provider's performance for only the dual eligible subgroup, allowing comparisons for specific performance to be better understood and compared to peers, or against state and national benchmarks.

Taken separately, each approach may provide an incomplete picture of disparities in care for a particular measure, but when reported together with overall quality performance, these results can give detailed information about where differences in care exist. Using dual eligibility as an example, a healthcare provider may underperform when compared to national averages for their dual eligible population (''across-provider'' disparity), but if they also underperform for patients who are not dual eligible, the measured difference, or ''within-provider'' disparity, could be negligible even though performance for the group that has been historically marginalized remains poor. In this case, simply providing stratified within-provider results could show little difference in care between patient groups seen by the provider but the combined results show the provider is underperforming on care for some patients compared to other providers.

Similar approaches have been recommended by the Assistant Secretary of Planning and Evaluation (ASPE) as ways to measure health

Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf*.

[354] Centers for Medicare & Medicaid Services, Office of Minority Health. Racial, Ethnic, & Gender Disparities in Health Care in Medicare Advantage. (2021). Available at: *https://www.cms.gov/files/document/racial-ethnic-gender-disparities-health-care-medicare-advantage.pdf*.

[355] QualityNet. Disparity Methods Confidential Reporting Overview. Available at: *https://qualitynet.cms.gov/inpatient/measures/disparity-methods*.

[356] Centers for Medicare & Medicaid Services. (2015). Risk Adjustment Fact Sheet. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/Risk-Adjustment-Fact-Sheet.pdf*.

equity in their 2020 Report to Congress.[357] In their report, ASPE suggested measuring and reporting quality specifically for beneficiaries with social risk factors, stratifying measures by social risk factors, and encouraging the development of health equity measures such as these for incorporation into quality reporting programs.

We are especially sensitive to the need to ensure all disparity reporting avoids measurement bias. Stratified results must be carefully examined for potential measurement or algorithmic bias [358] that is introduced through stratified reporting. Furthermore, results of stratified reporting must be evaluated for any type of selection bias that fails to capture disparity due to inadequate representation of subgroups of patients in measure cohorts. As part of the implementation of any type of measure stratification, we would carefully examine stratified results and methods to mitigate the potential for drawing incorrect conclusion from results.

3. Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting Across CMS Quality Reporting Programs

We are considering expanding our efforts to provide stratified reporting for additional clinical quality measures, provided they offer meaningful and valid feedback to healthcare providers on their care for populations that may face social disadvantage or other forms of discrimination or bias. Further development of stratified reporting of healthcare quality measures can provide healthcare providers with more granular results that support targeting resources and initiatives to improve health equity as a means to improving the overall quality of care. We are mindful that it may not be possible to calculate stratified results for all quality measures, or that there may be situations where stratified reporting may not be desired. To help inform prioritization of the next generation of candidate measures for stratified reporting, we solicited feedback on several systematic principles under consideration that we believe will help us prioritize measures for disparity reporting across quality programs.

These considerations would help guide the use of stratified measure results to provide information on healthcare disparities broadly across our quality programs. While we aim to standardize approaches where possible, disparity identification requires an understanding of the specific context and measures used by each program. To ensure that results provide the most actionable data possible, and to limit the potential for the introduction of bias, we believe decisions about how to identify and prioritize measures for possible stratification be made at the program level.

- *Prioritize Existing Clinical Quality Measures*—When considering disparity reporting of stratified quality measures, there are several advantages to focusing on measures that we have already, through notice and comment rulemaking, adopted for one or more CMS quality programs. These measures assess the quality of care on agreed upon topics for quality measurement specific to a quality program setting. These measures have gone through an extensive development process and validation testing with significant opportunity for public input. Adapting these existing quality measures to measure disparity through stratification maintains adherence to the measurement priorities identified through expert review and validation completed through measure development and testing. The application of measure stratification to these measures would also minimize any new reporting burden on healthcare providers.
- *Prioritize Measures with Identified Disparity in Treatment or Outcomes for the Selected Social or Demographic Factor*—Candidate measures for stratification be supported by evidence of underlying healthcare disparities in the procedure, condition, or outcome being measured. A review of peer-reviewed research studies be conducted to identify disparities related to treatment, procedure, or outcome associated with the measure, and carefully consider both social risk factors and patient demographics. In addition, analysis of Medicare-specific data be done to demonstrate evidence of disparity in care among the Medicare population. In addition, consideration also be given to conditions that have highly disproportionate prevalence in certain populations.
- *Prioritize Measures with Sufficient Sample Size to Allow for Reliable and Representative Comparisons*—Sample size holds specific significance for statistical calculations; however, it holds additional importance in the context of disparity reporting. Candidate measures for stratification will need to have sufficient cohort sample size to ensure that reported results of the disparity calculation are reliable and representative of the healthcare provider's patient population. This may be challenging if cohorts with a given social risk factor are small.

Carefully establishing reliability and representation standards for measure reporting is important for considering measures to stratify. Reliability, in this case, refers to the minimum case count needed to achieve reliable results. Metrics for reliability are used in non-stratified quality measure reporting, such as when measures require a certain number of procedures for their rates to be considered reliable. The use of a reliability standard for disparity reporting will ensure consistently reliable results are calculated.

Representation standards are also important and may involve requiring a minimum number or percent of healthcare providers or patients to be eligible to receive stratified results with reliable estimates before a measure is considered for disparity reporting. This requirement aims to ensure that meaningful comparisons can be made. As we noted previously, when only a small proportion of healthcare providers can receive statistically significant results, it may not be prudent for quality programs to pursue stratified reporting for that particular measure. Doing so can create challenges when generalizing rates of disparity for conditions or procedures when only a small proportion of a healthcare provider's results are considered. If, for example, only 10 percent of healthcare providers can report results, results must be clearly presented to ensure they are not understood to represent disparity in care for the measurement taking place in all care settings, as shown in this example, where 90 percent of them would not be included in reporting.

Quality programs may further consider measures for disparity reporting based on the size of the calculated disparity by prioritizing measures for stratification that show large differences in care between patient groups. Large differences in care for patients along social or demographic lines may indicate high potential that targeted initiatives could be effective. However, measures with disparities of smaller magnitude but with large cohorts affect many patients because they may have very large aggregate impacts on the national scale.

[357] ASPE. (2020). Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program: The Second of Two Reports Required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195191/Second-IMPACT-SES-Report-to-Congress.pdf*.

[358] Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. Science. 2019;366(6464):447–53.

• *Prioritize Outcome Measures and Measures of Access and Appropriateness of Care*— Quality measurement in CMS programs often focus on outcomes of care, such as mortality or readmission. Outcomes measures remain a priority in the context of disparities measurement. However, measures that focus on access to care, when available, are also critical tools for addressing healthcare disparities. Measures that address healthcare access can counterbalance the risk of creating perverse incentives. If only differences in care between groups are measured, performance on a measure of disparity could be improved by limiting access to care for high-risk patients in the populations that are historically underserved or marginalized.

To complement stratification of measures focused on clinical outcomes, quality programs may consider prioritizing measures with a focus on access to or the appropriateness of care. These measures, when reported in tandem with clinical outcomes, would provide a broader picture of care provided by a healthcare provider, illuminate potential drivers of performance, and highlight organizations that fail to address barriers in access to care for groups that have been historically marginalized. We acknowledge that the measurement of access and appropriateness of care is a growing field, and that there are currently a limited number of developed quality measures on these topics. However, as our ability to measure these facets of healthcare improves, we expect that they will be high priority for measure stratification.

4. Principles for Social Risk Factor and Demographic Data Selection and Use

There are a wide array of non-clinical drivers of health known to impact patient outcomes, including social risk factors such as socioeconomic status, housing availability, and nutrition, as well as marked inequity in outcomes based on patient demographics such as race and ethnicity, being a member of a minority religious group, geographic location, sexual orientation, and gender identity, religion, and disability status.[359] [360] [361] [362] [363] [364] [365] [366] [367] The World Health Organization (WHO) defines social risk factors as ''non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life.''[368] These include factors such as income, education, job security, food security, housing, social inclusion and non-discrimination, access to affordable health services, and any others. Research has indicated that these social factors may have as much or more impact on health outcomes as clinical care itself.[369] [370] Additionally, differences in outcomes based on patient race and ethnicity have been identified as significant, persistent, and of high priority for CMS and other federal agencies.[371]

Identifying and prioritizing specific indicators of social risk or demographic variables to consider for stratified analyses and measure reporting can be challenging due to the large number of variables identified in the literature as potential risk factors for disparities in health care and poorer health outcomes. And yet, the limited availability of data for many self-reported social risk factors and demographic factors across the healthcare sector further complicates our ability to choose effective metrics to evaluate disparity.

Disparity reporting in the Hospital IQR Program has focused on stratification by dual eligibility for Medicare and Medicaid. Dual eligibility has been used in this and other CMS quality programs as an indicator of financial risk, as the majority of Medicaid beneficiaries are eligible based on meeting thresholds for low patient income and/or assets. The use of dual eligibility is consistent with recommendations from ASPE's First Report to Congress which was required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185).[372] This report found that, in the context of value-based purchasing (VBP) programs, dual eligibility, as an indicator of social risk, was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested.

Financial risk is only one metric of social risk, and stratification of quality measures by additional social risk factors and demographics (such as race, ethnicity, language, religion, sexual orientation, and gender identity) or disability, is important to provide more granular information for healthcare providers to act upon. As we consider prioritizing and expanding the variables used for measure stratification, we will carefully consider both social risk factors and patient demographics as well as other variables associated with historic disadvantage in healthcare, such as disability status.

As noted previously, a growing body of literature identifies the association between social risk factors and demographic variables with poorer health outcomes.[373] [374] [375] While social

[359] Joynt KE, Orav E, Jha AK. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.

[360] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and thirty-day outcomes after acute myocardial infarction, heart failure, and pneumonia: retrospective cohort study. British Medical Journal, 346.

[361] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. New England Journal of Medicine, 371(24):2298–2308.

[362] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs, 40(2): 307–316.

[363] Rural Health Research Gateway. (2018). Rural communities: Age, income, and health status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf*.

[364] HHS Office of Minority Health (2020). 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf*.

[365] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. medRxiv [Preprint]. 2020.07.21.20159327. doi: 10.1101/2020.07.21.20159327. PMID: 32743608; PMCID: PMC7386532.

[366] Vu M. et al. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6). doi: 10.1089/jwh.2015.5517.

[367] Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016) The Association between Discrimination and the Health of Sikh Asian Indians. Health Psychology, 35(4), 351–355. *https://doi.org/10.1037/hea0000268*.

[368] World Health Organization. Social Determinants of Health. Available at: *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1*.

[369] Hood, C., Gennuso K., Swain G., Catlin B. (2016). County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. Am J Prev Med. 50(2):129–135. doi:10.1016/j.amepre.2015.08.024.

[370] Chepaitis, A.E., Bernacet, A., Kordomenos, C., Greene, A.M., Walsh, E.G. (2020). Addressing social determinants of health in demonstrations under the financial alignment initiative. RTI International. Available at: *https://innovation.cms.gov/data-and-reports/2021/fai-sdoh-issue-brief*.

[371] White House. (2021). Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Available at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[372] Office of the Assistant Secretary For Planning and Evaluation. (2016). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs*.

[373] National Academies of Sciences, Engineering, and Medicine. (2016). Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858*. Available at:

risk factors and demographic variables are both associated with worse healthcare outcomes and experiences, they are distinct constructs, and be identified, measured, and reported as such. Patient demographic variables such as race and ethnicity are often identified as indicators of social risk driven by the differences in care received by persons who belong to minority racial and ethnic groups. The disparity in outcomes can be attributed to many factors, including discrimination in the healthcare system, challenges accessing quality healthcare, and societal inequity in other factors connected to social risk. Attributing differences in outcomes to race may inappropriately place the driver of poorer health outcomes on the patient, rather than on structural factors, such as racism in society and the healthcare system that drive the provision of lower quality care.[376] It is important, in identification of non-clinical drivers of health, to identify that race and ethnicity are not the social risk factor, but markers of exposure to other factors.

In prioritizing among social risk factors and demographic variables, disability, and other markers of disadvantage for stratified reporting, we anticipate that each individual quality program would design an approach appropriate to their care setting. We strive to operationalize our programs consistently where possible to decrease the burden on healthcare providers, however, the deeply contextual nature of this type of reporting may require the development of an approach specific to the quality programs based on care setting, patient population, and data availability.

The availability of data is a crucial consideration when examining data sources for use in stratified quality reporting. In many cases, the lack of available patient-reported data on patient social risk or demographic variables limits the ability to conduct disparity analyses. While improving the collection of patient-reported demographic information and information on social risk is an ongoing goal, other methods and data sources for estimating social risk (as described further in this section) could potentially fill in gaps in existing data sets, and could include area-based indicators or imputation techniques that use existing information about patient populations to estimate approximations about related population information. Each of these types of data sources have advantages and disadvantages.

Patient-reported data are considered to be the gold standard for evaluating care for patients with social risk factors or who belong to certain demographic groups as this is an accurate and preferred way to attribute social risk.[377] Currently, there are many efforts underway to further develop data standards for collection for self-reported patient social risk and demographic variables. Yet, given that national data sources of reliable, self-reported data are not yet available, we also intend to consider other options for social risk factor data. We note efforts to standardize the collection of demographic and social risk factor data include prior work done by both CMS and the Office of the National Coordinator for Health Information Technology (ONC) with federal and private partners to better collect and leverage data on social risk. This work includes: (1) The development of an Inventory of Resources for Standardized Demographic and Language Data Collection;[378] [379] (2) CMS' work to support specialized International Classification of Diseases, (ICD) 10th Revision, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental drivers of health;[380] and (3) the CMS sponsorship of several initiatives to statistically estimate race and ethnicity information when it is absent.[381] [382]

One example of improving sources of data come from the certified health IT utilized by hospitals to meet the requirements of the Promoting Interoperability program. This includes health IT certified to the ''demographics'' certification criterion (45 CFR 170.315(a)(5)), which provides for the capability to record race and ethnicity at a detailed level of granularity consistent with the Centers for Disease Control and Prevention's (CDC) Race & Ethnicity—CDC code system. This code system includes more than 900 concepts for race and ethnicity, which gives patients very specific options for self-identifying their demographic information. The 900 concepts are organized in a way to eventually ''roll up'' to the Office of Management and Budget's (OMB) minimum categories for race and ethnicity,[383] which can support aggregation and reporting needs when the OMB standard is necessary. It also includes social, psychological, and behavioral standards in health IT certification criteria (80 FR 62601), providing interoperability standards (LOINC [Logical Observation Identifiers Names and Codes] and SNOMED CT [Systematized Nomenclature of Medicine—Clinical Terms]) for financial strain, education, social connection and isolation, and others. The Agency for Healthcare Research and Quality (AHRQ) has also worked with the Gravity Project which is a multistakeholder effort to expand capabilities to capture additional drivers of health data elements, to identify and harmonize social risk factor data for interoperable electronic health information exchange for electronic health record (EHR) fields,[384] and make recommendations on the expansion of

https://www.nap.edu/catalog/21858/accounting-for-social-risk-factors-in-medicare-payment-identifying-social.

[374] Office of the Assistant Secretary For Planning and Evaluation. (2016). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[375] Office of the Assistant Secretary For Planning and Evaluation. (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[376] Gee G.C., Ford C.L. (2011). Structural Racism and health inequities: Old Issues, New Directions. Du Bois Review: Social science research on race, 8(1), 115–132. Available at: *https://doi.org/10.1017/S1742058X11000130.*

[377] Jarrín OF, Nyandege AN, Grafova IB, Dong X, Lin H. (2020). Validity of race and ethnicity codes in Medicare administrative data compared with gold-standard self-reported race collected during routine home health care visits. Med Care, 58(1):e1–e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

[378] Centers for Medicare & Medicaid Services. (2020). Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[379] The Office of the National Coordinator for Health Information Technology (ONC). Health IT Standards Bulletin. *HealthIT.gov:* 2021. URL: *https://www.healthit.gov/sites/default/files/page/2021-05/Standards_Bulletin_2021-2.pdf.*

[380] Centers for Medicare & Medicaid Services (2019). Utilization of Z Codes for Social Determinants of Health among Medicare Fee-for-Service Beneficiaries, 2019. Available at: *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[381] Centers for Medicare & Medicaid Services (2021). A New Method to Improve measurement of Race-and-Ethnicity in CMS Data and Applications to Inequities in Quality of Care. Available at: *https://www.cms.gov/files/document/new-method-improve-measurement-race-and-ethnicity-cms-data-and-applications-inequalities-quality.pptx.*

[382] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[383] **Federal Register**. (1997). Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity. Available at: *https://www.federalregister.gov/documents/1997/10/30/97-28653/revisions-to-the-standards-for-the-classification-of-federal-data-on-race-and-ethnicity.*

[384] Gravity Project. Available at: *https://thegravityproject.net/.*

the ICD–10 (International Classification of Diseases, 10th Revision) Z-codes, the alphanumeric codes used worldwide to represent diagnoses, to include additional social risk diagnoses.[385]

We expect to continue evaluating patient-reported sources of social risk and demographic information. We are also considering three sources of social risk and demographic data that would allow us to report stratified measure results:

• *Billing and Administrative Data*—The majority of quality measurement tools used in our quality programs focus on utilizing existing claims and administrative data for Medicare beneficiaries. Using these existing data to assess disparity, for example by the use of dual enrollment for Medicare and Medicaid, allows for high impact analyses with negligible healthcare provider burden. There are, however, limitations in these data's usability for stratification analysis. CMS's current administrative race and ethnicity data have been shown to have historical inaccuracies due to limited collection classifications and attribution techniques, and are generally considered not to be accurate enough for stratification and disparity analyses.[386] International Classification of Diseases, 10th Revision (ICD–10) codes for socioeconomic and psychosocial circumstances (''Z codes'' Z55 to Z65) represent an important opportunity to document patient-level social risk factors in Medicare beneficiaries, however, they are rarely used in clinical practice, limiting their usability in disparities measurement.[387] If the collection of social risk factor data improves in administrative data, we will continue to evaluate its applicability for stratified reporting in the future.

Dual eligibility is a widely used proxy for low socioeconomic status and is an exception to the previously discussed limitations, making it an effective indicator for worse outcomes due to low socioeconomic status. The use of dual eligibility in social risk factor analyses was supported by ASPE's First and Second Reports to Congress.[388] [389] These reports found that in the context of VBP programs, dual eligibility, as an indicator of social risk, was among the most powerful predictor of poor health outcomes among those social risk factors that ASPE examined and tested.

• *Area-based Indicators of Social Risk Information and Patient Demographics*—Area-based indicators pool area-level information to create approximations of patient risk or describe the neighborhood or context that a patient resides in. Popular among them are the use of the American Community Survey (ACS), which is commonly used to attribute social risk to populations at the ZIP code or Federal Information Processing Standards (FIPS) county level. Several indices, such as the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index,[390] Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry Social Vulnerability Index (CDC/ATSDR SVI),[391] and Health Resources and Services Administration Area Deprivation Index,[392] combine multiple indicators of social risk into a single score which can be used to provide multifaceted contextual information about an area and may be considered as an efficient way to stratify measures that include many social risk factors.

• *Imputed Sources of Social Risk Information and Patient Demographics*—Imputed data sources use statistical techniques to estimate patient-reported factors, including race and ethnicity. In the case of race and ethnicity, indirect estimation improves upon imperfect and incomplete data by drawing on information about a person's name and address and the linkage of those variables to race and ethnicity. One such tool is the Medicare Bayesian Improved Surname Geocoding (MBISG) method (currently in version 2.1), which combines information from administrative data, surname, and residential location to estimate patient race and ethnicity.[393] We have customized this tool for the Medicare population to improve our existing administrative data on race and ethnicity.

The MBISG 2.1 method does not assign a single race and ethnicity to an individual; instead, it generates a set of six probabilities, each estimating how the individual would self-identify if provided with a set of racial and ethnic groups to choose from including: American Indian or Alaska Native, Asian or Pacific Islander, Black, Hispanic, Multiracial, and White. In no case would the estimated probability be used for making inferences about a specific beneficiary; only self-reported data on race and ethnicity be used for that purpose. However, in aggregate, these results can provide insight and accurate information at the population level, such as the patients of a given hospital, or the members of a given plan. MBISG 2.1 is currently used by our Office of Minority Health (OMH) to undertake various analyses, such as comparing scores on clinical quality of care measures from the Healthcare Effectiveness Database and Information Set (HEDIS) by race and ethnicity for Medicare Part C/D health plans, and in developing a Health Equity Summary Score (HESS) for Medicare Advantage (MA) health plans.[394]

While the use of area-based indicators and imputed data sources are not meant to replace efforts to improve patient-level data collection, we are considering how they might be used to begin

[385] Centers for Medicare and Medicaid Services. (2020). Z Codes Utilization among Medicare Fee-for-Service (FFS) Beneficiaries in 2017. Available at: *https://www.cms.gov/files/document/cms-omh-january2020-zcode-data-highlightpdf.pdf.*

[386] Jarrín OF, Nyandege AN, Grafova IB, Dong X, Lin H. (2020). Validity of race and ethnicity codes in Medicare administrative data compared with gold-standard self-reported race collected during routine home health care visits. Med Care, 58(1):e1–e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

[387] Centers for Medicare & Medicaid Services, Office of Minority Health. (2021). Utilization of Z codes for social determinants of health among Medicare fee-for-service beneficiaries, 2019. Available at: *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[388] Office of the Assistant Secretary for Planning and Evaluation. (2016). Social risk factors and performance under Medicare's value-based purchasing programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[389] Office of the Assistant Secretary For Planning and Evaluation. (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[390] Bonito A., Bann C., Eicheldinger C., Carpenter L. (2008). Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare & Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality.

[391] Flanagan, B.E., Gregory, E.W., Hallisey, E.J., Heitgerd, J.L., Lewis, B. (2011). A social vulnerability index for disaster management. Journal of Homeland Security and Emergency Management, 8(1). Available at: *https://www.atsdr.cdc.gov/placeandhealth/svi/img/pdf/Flanagan_2011_SVIforDisasterManagement-508.pdf.*

[392] Center for Health Disparities Research. About the Neighborhood Atlas. Available at: *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[393] Haas A., Elliott M.N., Dembosky J.W., Adams J.L., Wilson-Frederick S.M., Mallett J.S. et al. (2019). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res, 54(1):13–23. doi: 10.1111/1475–6773.13099. Epub 2018 Dec 3. PMID: 30506674; PMCID: PMC6338295. Available at: *https://pubmed.ncbi.nlm.nih.gov/30506674/.*

[394] Agniel D., Martino S.C., Burkhart Q., Hambarsoomian K., Orr N., Beckett M.K, et al. (2021). Incentivizing excellent care to at-risk groups with a health equity summary score. J Gen Intern Med, 36(7):1847–1857. doi: 10.1007/s11606–019–05473–x. Epub 2019 Nov 11. PMID: 31713030; PMCID: PMC8298664. Available at: *https://pubmed.ncbi.nlm.nih.gov/31713030/.*

population-level disparity reporting of stratified measure results while being conscientious about data limitations.

Imputed data sources, particularly when used to identify patient populations for measurement, must be carefully evaluated for their potential to negatively affect the populations being studied. For this reason, imputed data sources only be considered after a significant validation study has been completed, including evaluation by key stakeholders for face validity, and any calculations that incorporate these methods be continuously evaluated for the accuracy of their results and the necessity of their use. While neither imputed nor area-level geographic data be considered a replacement for improved data collection, researchers have found their use to be a simple and cost-efficient way to make general estimations of social risk at a community level.[395] In place of patient-level information when it is not available, the combination of several sources of imputed or area-level data can provide actionable estimations of social risk of a population.

5. Identification of Meaningful Performance Differences

In examining potential ways to report healthcare disparity data, that is, the results of quality measure stratification, we expect to consider different approaches to identifying meaningful differences in performance. Stratified results can be presented in several ways to describe to providers how well or poorly they are performing, or how they perform when compared to other care facilities. For this reason, it is important to identify how best to present meaningful differences in performance for measures of disparity reporting. While we aim to use standardized approaches where possible, we also expect that decisions about how to identify meaningful differences in performance would ultimately be tailored to each individual program. We welcomed feedback on the benefits and limitations of the possible disparity reporting approaches we described in this RFI.

- *Statistical Differences*—When aiming to examine differences in disparities results among healthcare providers, the use of statistical testing can be helpful. There are many statistical approaches that can be used to reliably group results, such as using confidence intervals, creating cut points based on standard deviations, or using a clustering algorithm. Importantly, these approaches may result in groupings that are statistically different, but not meaningfully different depending on the distribution of results.
- *Rank Ordering and Percentiles*—Ordering healthcare providers in a ranked system is another option for reporting disparity results in a meaningful way. In this system, healthcare providers could be ranked based on their performance on disparity measures to quickly allow them to compare their performance to other similar healthcare providers. We may consider using an ordered system to report healthcare provider results by categorizing healthcare providers into groups, for example, into quintile or decile groups. This approach works well as a way for healthcare providers to easily compare their own performance against others; however, a potential drawback is that it does not identify the overall magnitude of disparity. For example, if a measure shows large disparity in care for patients based on a given factor, and that degree of disparity has very little variation between healthcare providers, the difference between the top and bottom ranked healthcare providers would be very small even if the overall disparity is large.
- *Threshold Approach*—A categorization system could also be considered for reporting disparity results. In this system, healthcare providers could be grouped based on their performance using defined metrics, such as fixed intervals of results of disparity measures, indicating different levels of performance. Using a categorized system may be more easily understood by stakeholders by giving a clear indication that outcomes are not considered equal. However, this method does not convey the degree of disparity between healthcare providers or the potential for improvement based on the performance of other healthcare providers. Furthermore, it requires a determination of what is deemed 'acceptable disparity' when developing categories.
- *Benchmarking*—Benchmarking, or comparing individual results to, for example, state or national averages, is another potential reporting strategy. This type of approach could be done, especially in combination with a ranked or threshold approach, to give healthcare providers more information about how they compare to the average care for a patient group.

Another consideration for each of these approaches is grouping similar care settings together for comparison through a peer grouping step, especially if a ranked system is used to compare healthcare providers. Some stakeholders have stated that comparisons between healthcare providers have limited meaning if the healthcare providers are not similar, and that peer grouping would improve their ability to interpret results. Overall, the value of peer grouping must be weighed against the potential to set different standards of meaningful disparity among different care settings.

6. Guiding Principles for Reporting Disparity Results

Confidential reporting for a short period that is not followed by public reporting of the same measure data is one approach we have used for newly adopted measures in a CMS quality program to give healthcare providers an opportunity to become more familiar with calculation methods and to begin improvement activities before their measure results are publicly reported. Providing early results to healthcare providers is an important way to provide healthcare providers the information they need to design impactful strategies to reduce disparity. Public reporting is a statutory requirement in all of our quality programs. Public reporting provides all stakeholders with important information on healthcare provider quality, and in turn, relies on market forces to incentivize healthcare providers to improve and become more competitive in their markets.

Payment accountability for performance is also statutorily required in some of our quality programs. Payment accountability refers to tying payment to the results of quality measure performance, and in general rewards better performance with higher payment rates. Payment accountability allows us to reward healthcare providers for having low disparity rates and performing well for vulnerable patient groups.

We are exploring whether it would be prudent to first confidentially report all stratified measure results, where adopted into a quality reporting program, to give healthcare providers an opportunity to understand those results so they can begin to implement programs to reduce disparities before we report the results publicly.

We also believe it is important to report stratified measure data alongside overall measure results. Review of both overall measure results along with stratified results can illuminate greater levels of detail about quality of care for subgroups of patients, providing

[395] Bi, Q., He, F., Konty, K., Gould, L.H., Immerwahr, S., & Levanon Seligson, A. (2020). ZIP code-level estimates from a local health survey: Added value and limitations. Journal of Urban Health: Bulletin of the New York Academy of Medicine, 97(4), 561–567.

important information to drive quality improvement. Unstratified quality measure results address general differences in quality of care between healthcare providers and promote improvement for all patients, but unless stratified results are available, it may be unclear whether there are subgroups of patients that would benefit most from targeted quality improvement initiatives. Notably, even if overall quality measure scores were to improve, without identifying and measuring differences in outcomes between groups of patients, it could be impossible to track progress in reducing disparity between patients with and without heightened risk of poor outcomes due to social factors.

7. Solicitation of Comments

The goal of this RFI was to describe key considerations in determining how to develop future policies around the use of measure stratification as one quality measurement tool to address healthcare disparities and advance health equity across our quality programs. This is important as a means of setting priorities and expectations for the use of stratified measure results.

We invited general comments on the principles and approaches listed previously, as well as additional recommendations about disparity measurement or stratification guidelines suitable for overarching consideration across our quality programs. Specifically, we invited comment on:

- Overarching goals for measuring disparity that be considered across CMS quality programs, including the importance of pairing stratified results with overall measure results to evaluate gaps in care among groups of patients attributed to a given healthcare provider and comparison of care for a subgroup of patients across healthcare providers.
- Principles to consider for prioritization of measures for disparity reporting, including prioritizing stratification for: valid clinical quality measures; measures with established disparities in care; measures that have adequate sample size and representation among healthcare providers; and, measures that consider access and appropriateness of care.
- Principles to be considered for the selection of social risk factors and demographic data for use measuring disparities, include the importance of identifying new social risk factor and demographic variables to use to stratify measures. We also sought comment on the use of imputed and area-based social risk and demographic indicators for measure stratification when patient reported data are unavailable.
- Preferred ways that meaningful differences in disparity results can be identified or be considered.
- Guiding principles for the use and application of the results of disparity measurement such as providing confidential reporting initially.

We received comments on these topics.

Comment: Many commenters responded to the overarching goals for measuring disparity across CMS quality programs described in the RFI. In general, commenters supported the goals of measure stratification set out in the proposed rule and suggested that these efforts could lead to a better understanding of longitudinal, geographic and provider disparity trends. Commenters noted that stratification of applicable measures by social risk factors will support hospital decision making and encourage CMS to be more explicit in describing the relationship between stratification methods and the concept of ''health equity,'' as well as the implications of those views for the specific proposals being made. Commenters also suggested that these methods be designed to have the greatest impact possible on patient care and experience.

Many commenters supported considering multiple approaches to measuring healthcare disparities, specifically, using the existing ''within-provider'' and ''across-provider'' approaches included in the CMS Disparity Methods. Commenters supported the current use of dual-eligibility for Medicare and Medicaid as a stratification variable, but suggested stratification by additional social risk factors and noted that appropriate considerations for confounding factors be accounted for.

Many commenters urged that CMS consider any additional provider burden associated with disparity measurement and that CMS acknowledge the need to provide actionable, useful, consistent, valid, reliable, comparable, and robust measures and data. A commenter recommended that CMS establish consistent measures across CMS's various quality programs to reduce reporting burden and to enhance robustness of the data collected; however, other commenters agreed that approaches may need to be tailored to individual settings. Commenters expressed that there are many challenges in the implementation of stratified measure reporting and offered several comments and suggestions. Commenters noted the need for CMS to contextualize disparity results, the need for more resources for providers to address disparity results, and the potential utility of peer grouping especially when using approaches that compare performance across providers to allow for more 'like to like' comparisons.

A commenter suggested using performance thresholds and benchmarking for the entire patient population instead of performance threshold by subgroup like the ''across-provider'' approach.'' Another commenter suggested that, in order not to reward low-quality care, reductions in disparities be measured against total quality of care.

A commenter noted that the inclusion of health equity as a strategic goal in the FY 2023 IPPS/LTCH PPS proposed rule assumes a meaningful relationship between the processes and outcomes of care at the inpatient hospital level and the broad measures of population health that are generally subsumed under the concept of ''health equity.'' The commenter encouraged CMS to be more explicit in describing its views of this relationship, and the implications of those views for the specific proposals being made.

A few commenters opposed measure stratification or the direction of CMS's health equity efforts noting that ranking and comparing provider performance may lead to performance competition and gaming but may not result in improved care for patients. Another commenter noted that CMS could potentially create a healthcare provider ranking system based on the results of the nonmedical, social risk factors included in the stratification method but that this would be an unacceptable and inappropriate use of the healthcare system's resources.

Response: We appreciate the feedback and suggestions provided by the commenters regarding overarching goals for measuring disparity across CMS quality programs; particularly, the importance of balancing the pursuit of meaningful impact with burden reduction in implementation. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters emphasized the importance of avoiding measurement bias as a key goal for measuring disparity. Commenters expressed concerns that stratification, specifically when combined with the use of imputed data to identify demographic and social risk factors and variables, could lead to measurement bias, and potentially deepen inequities. Commenters recommended that CMS disclose methods and algorithms for imputed data to maintain consumer trust and confidence.

Several commenters suggested that methods be introduced to adjust quality measures and measurement tools for patient social risk or race and ethnicity. These commenters noted that this is important to ensure that providers, such as safety-net hospitals, who care for large proportions of patients with social risk factors are not unfairly penalized under these performance metrics.

Response: We appreciate the feedback and suggestions provided by the commenters regarding attention to the importance of avoiding measurement bias when stratifying measures in CMS programs. We will take commenters' feedback into consideration in future policy development.

We would also like to clarify that the RFI does not directly address risk adjustment for patient social factors or demographic variables within measures, which may set different expected quality results for persons with certain social risk factors, but rather discusses approaches to distinguish performance between groups to highlight underlying disparities.

Comment: Commenters responding to principles for the prioritization of measures for disparity reporting supported using existing clinical quality measures, particularly outcome measures and measures of access and appropriateness of care, as a guiding principle in selecting and prioritizing measures for quality reporting across CMS quality reporting programs.

A commenter expressed support for the proposed prioritization of existing clinical quality measures for disparity stratification, particularly those classified as outcomes measures and measures of access and appropriateness of care, rather than developing entirely new disparity-focused measures. The commenter stated that this will limit any additional administrative burden for facilities to understand, implement, and report new quality measures while focusing on the most meaningful results for patients.

A commenter appreciated CMS's efforts to test and validate these measures, though others cautioned the agency to balance reducing the burden of developing purpose-fit measures with potential problems or limitations in many existing measures and recommended that existing clinical measures be further reviewed and validated prior to implementation within CMS's reporting programs. Other commenters cautioned that individual measures' risk-adjustment methods must be assessed for their impact on disparity results.

Many commenters supported using measures with identified disparity in treatment or outcomes for the selected social or demographic factor as a guiding principle in selecting and prioritizing measures for quality reporting across CMS quality reporting programs. A commenter urged CMS to prioritize measures that relate to the conditions in which the inequities are starkest. Another commenter cautioned that measures with known disparities in care be judged carefully—that is, that reporting disparity results must be actionable, and not just be descriptive of large disparities. Several additional topics and conditions were suggested for disparity measurement, including maternal morbidity and mortality, sickle cell disease, cancer, cardiovascular disease, chronic kidney disease and End-Stage Renal Disease.

Response: We appreciate the feedback and suggestions provided by the commenters regarding the prioritization of quality measures for stratification; again, with particular appreciation for the importance of reducing burden in implementation. We will take commenters' feedback into consideration in future policy development.

Comment: Many commenters commented on priorities for selecting measures for stratification particularly related to sample size and reliability of measures. They supported using measures with sufficient sample size to allow for reliable and representative comparisons to be made.

Commenters noted that focusing on statistical reliability and representation meets two important criteria. First, the reportability and reliability of a measure will have an impact on how appropriate different types of reporting will be, and second, not reporting results for all providers due to statistical considerations risks drawing conclusions about disparity from an incomplete set of results. For example, disparity in hospitals with low sample sizes may not be calculated and reported, even if differences in care in this setting are the greatest. The commenters stated that unintended consequences of this approach could allow for disparities to go unnoticed in communities already historically disadvantaged and marginalized by the healthcare system.

Commenters suggested that CMS consider innovative applications of statistical methodologies for the design and analysis of small sample data including: (1) Research designs and analytic methods that can maximize statistical power for analyses of interventions conducted with small, culturally distinct samples—including dynamic wait list research designs, Bayesian approaches, matching, imputation, or increasing look back periods, (2) strategies for reducing error and bias in measures applied in studies with culturally distinct samples such as the Rasch Measurement Model, and (3) use of qualitative methods and mixed methods combining qualitative and quantitative data.

A commenter noted that statistical reliability and representative sampling are important but could prove difficult (depending on census composition) for facilities to maintain with fluctuating demographics and recommended that any representation standards be applied over the duration of the performance year to maximize the chance of capturing data on individuals with social risk factors.

A commenter noted that while blending performance across years also encourages sustained high quality, pooling data across years could dampen a provider's drive to improve if their recent better results are blended with older, poorer performance. The commenter noted that in such a case, the provider's improved performance would not be fully recognized in its payment incentive payment for several years and suggested that, in order to counter this disincentive, CMS could consider weighting the more recent years more heavily or CMS could also pool data across years only for low-volume providers, while reporting just the most recent year's performance for providers that meet a minimum count in a single year.

Response: We appreciate the feedback and suggestions provided by the commenters regarding sample size and representation in disparity analyses. We will take commenters' feedback into consideration in future policy development.

Comment: Commenters on principles for prioritizing measurement suggested that measures be prioritized for stratification based on many criteria, such as identifying measures that: target the most high-value and impactful measures; meaningfully advance health equity or reduce healthcare disparities; provide a person-centered and holistic view of quality, including consideration of Social Drivers of Health (SDOH) and experience of care; provide meaningful and usable information, or are linked to an intervention; are tailored to specific community needs and socioeconomic circumstances that focus on improvements within those populations rather than exist as flat standards to meet; and, incentivize work on disparities reduction and improvement rather than penalize providers and

payers who serve more patients that are socially-disadvantaged.

A commenter stated that CMS not prioritize measures for stratification based on the type of measure (for example, structure, process, outcome, access), but that CMS instead prioritize measures for stratification if disparities exist in these measures and they can be measured accurately and reliably. This commenter noted that while the trend has been towards prioritizing outcome and access measures, these measures are also highly susceptible to factors outside a provider's control.

Response: We appreciate the feedback and suggestions provided by the commenters regarding prioritization of measures for disparity reporting. We will take commenters' feedback into consideration in future policy development.

Comment: Commenters offered a variety of views regarding principles for social risk factor and demographic data selection and use in stratification. A commenter expressed support for CMS's ongoing work to collect and make data publicly available related to social risk factors that affect patient outcomes.

Commenters agreed with the examples of social risk factors in the proposed rule (88 FR 28482 through 28483), including our current use of dual eligibility for Medicare and Medicaid as a social risk factor. Commenters also recommended that CMS use other financial risk factors in addition to dual eligibility, because the commenters believed that dual eligibility is better understood as a proxy for extreme financial risk.

Commenters suggested that CMS work to enhance the use of SDOH Z-codes for use in disparity reporting. that CMS work to enhance the capture of standardized data sets, and that CMS conduct research to identify the factors that have disproportionate impact on health outcomes and prioritize their collection. Commenters also suggested CMS review tools used to capture patient demographic and social risk factors that are validated and widely used but noted that ideally providers have the ability to choose the tool that best suit their patient population. Other commenters recommended that CMS explore using existing data, such as SSDOH Z-codes, before imposing new data reporting requirements.

Commenters suggested the use of additional social risk factors such as broadband internet access, social isolation, vision, mental health status, immigration status, and health literacy. Commenters suggested using gender as a social risk factor (as well as a demographic variable).

Commenters recommended that CMS explore using existing data before imposing new data reporting requirements.

Response: We appreciate the feedback and suggestions provided by the commenters regarding selection of social risk factors to use for measure stratification. We will take commenters' feedback into consideration in future policy development.

In addition we want to note that conceptually, equity related terms, such as ''health related social needs'', ''social determinants of health'', and ''social risk factors'' are all used to describe upstream factors that can adversely affect the health of individuals and communities (87 FR 28497). These terms are often conflated and used interchangeably and the variety of terms can create confusion, prompting some leaders in the field to adopt ''drivers of health'' instead. In the future, CMS is considering using ''drivers of health'' terminology to more holistically capture aforementioned and related concepts, while minimizing potential misinterpretation or negative connotation.

Comment: Several commenters addressed the identification of new demographic variables. Many commenters agreed that the collection of race and ethnicity data as well as data regarding the other demographic variables discussed in the preamble of the proposed rule was needed and will be essential for tracking disparities as well as guiding the design and application of culturally specific public health approaches. A commenter suggested that CMS add tribal membership as a variable.

Other comments suggested using current OMB race and ethnicity standards. A few commenters believed that CMS ensure collection of data on race and ethnicity, as well as certain other demographic data including patients' disability status, sexual orientation, gender identity, and physical and cogitative disabilities.

A commenter believed that ''race'' and ''ethnicity'' are so overly broad, vague, and ill-defined that, even in combination with other indicators, they are unlikely to provide useful information and may even obscure individual experience to the detriment of individualized patient care.

Some commenters supported using imputation, or estimation, methods for demographic variables. A commenter stated that CMS use strong, vetted algorithms for indirect/imputed data attribution. Another commenter noted that the indirect estimations as described in the proposed rule have very high predictiveness statistics and are often used in other facets of health research and analysis, including the annual report on Racial, Ethnic, & Gender Disparities in Health Care in Medicare Advantage. The commenter believed that these estimations are largely built on assumptions and that such algorithms often have issues with how race and ethnicity is defined and how the data are collected. Because self-reported race and ethnicity data are the gold standard and not be replaced with less reliable estimations, this commenter recommended that CMS move away from utilizing indirect estimations to collect race and ethnicity data and rather focus on efforts to promote collection of self-reported data in hospital settings.

Some commenters did not support using estimated patient race and ethnicity. Several commenters believed that estimating an individual's race or ethnicity based on name and geography is inappropriate. A commenter expressed several specific concerns regarding CMS's potential use of the Medicare Bayesian Improved Surname Geocoding (MBISG) model to estimate race and ethnicity for the purpose of risk stratification, and recommended CMS review the Urban Institute's Design Thinking Workshop on the Ethics of Imputation and Related Methods and subsequent report, ''Five Ethical Risks to Consider before Filling Missing Race and Ethnicity Data.''

Response: We appreciate the feedback and suggestions provided by the commenters regarding selection of demographic variables to use for measure stratification, and acknowledge the complexities involved in accurately capturing race, ethnicity, and other nuanced demographic information. While we will continue to explore rigorous estimation methods, we are committed to improving the collection and reporting of self-reported data as well as its use for risk stratification and other quality measurement purposes. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters expressed appreciation for CMS's identification of systemic racism as a driver of inequitable health. A commenter believed that data analysis include proactive steps to explicitly name racism and longstanding structural racism as root causes of inequities when interpreting and communicating findings, and whenever possible, make clear that observed health inequities are not due to biological traits, gender identities or

other characteristics of ethnically and racially diverse individuals or groups.

Commenters suggested CMS be wary of quality adjustment policies based on race or ethnicity due to the potential of measurement bias or other unintended consequences related to the implementation of well-intentioned models that may be biased.

Commenters believed that regular and ongoing implicit and explicit bias training for all healthcare team members is critical to addressing disparities and pursuing equity, and additional training will be necessary to support collecting patient-reported social risk and demographic data.

Response: We appreciate the feedback and suggestions provided by the commenters regarding the identification of structural racism as a driver of inequitable health, and agree that addressing the impact of racism, bias, and other forms of discrimination must be centered in the pursuit of health equity across CMS quality programs. We will take commenters' feedback into consideration in future policy development.

Comment: Commenters agreed with CMS that the availability of data on patient demographics and social risk factors is a crucial consideration when choosing variables to use for stratifying quality measures. Commenters agreed that patient self-reported data are preferred and are the gold standard because they are the most accurate and reflect a patient-centered focus; however, many clinicians already find it difficult to collect this information from their patients due to workflow issues, resource constraints, and the reluctance of some patients to self-report demographic and social risk data.

Commenters offered suggestions regarding how to improve data self-reporting. Commenters suggested CMS consider opportunities for consumer education and notification on the importance of self-reported data, and that any entities that will be collecting and using these data also be prepared to address the privacy and security of the data.

Commenters noted the difficulty in collecting patient data. A commenter recommended that CMS consider how it can support hospitals and other providers to improve the collection of patient self-reported social risk and demographic data, potentially by working with stakeholders to identify and share best practices on consumer-centered data collection approaches and workflows to expand and improve available options for demographic and social risk data collection. The commenter also recommended that CMS make efforts to ensure the data can be collected and reported efficiently and without undue burden.

A commenter stated that while that patient-level data remain the gold standard, depending on the proposed application, imputed data could have some potential utility to fill gaps in availability. The commenter expressed reluctance to support the use of imputed indices with approaches like risk adjustment, peer grouping, and other comparative performance applications unless CMS tests their use on specific measures and scoring methodologies.

Several commenters expressed some support for the use of the Health Resources and Services Administration Area Deprivation Index (ADI). A commenter stated that tools like the ADI have shown some utility and are worth consideration, but that the literature is less clear on the validity and utility of imputing individual race, ethnicity, or other variables. Commenters suggested that CMS avoid public reporting of disparity reports that use imputed data sources because this could unintentionally introduce measurement bias or discourage patients from selecting providers that care for patients in communities that have been marginalized.

Commenters urged that CMS adopt and endorse the Office of the National Coordinator for Health Information Technology's (ONC's) 2015 Edition standards for collecting disaggregated data for all hospitals and for all CMS quality programs. A commenter noted that the ONC's 2015 Edition Health Information Technology Certification Criteria Final Rule, the ''2015 Edition'' establishes HIT certification requirements that include full disaggregation of race and ethnicity, language, sexual orientation, gender identity, and social and behavioral risk factors.

Response: We appreciate the feedback and suggestions provided by the commenters regarding the availability of social risk and demographic data for use in stratified reporting. We especially recognize the importance of establishing and sustaining trust in the collection of such data to ensure both patients and providers understand intentions for its use and opportunities for impact. We will take commenters' feedback into consideration in future policy development.

Comment: Commenters had significant feedback on ways to identify meaningful performance differences in stratified disparity results. Commenters suggested that CMS work to develop metrics for measuring specific disparities and requested that CMS perform analyses with various reporting approaches—including statistical differences, rank ordering and percentiles, threshold, and benchmarking. A commenter also stated that the field needs to develop science and analytics to understand if a difference in performance on a given measure is a true disparity in care that is statistically significant. A commenter recommended that CMS conduct analyses to compare the results of different methods for identifying meaningful differences and publish the results of these analyses for stakeholder review and public comment.

A commenter stated that the identification of ''meaningful,'' included at least two major concepts—one is clinical importance (including lives saved, quality-adjusted life years gained, numbers of patients affected) and the other is size of disparity. The commenter suggested that not all available healthcare ''performance'' measures truly reflect performance by the measured entities in a clear and meaningful way and that this is particularly the case for many outcome measures that focus on endpoints removed both in time and location from the hospital providing care.

A few commenters recommended that CMS create a minimum threshold of acceptability from a statistical standpoint that defines what would constitute a disparity. More specifically, a commenter suggested that CMS adopt and use metrics for which success is not solely based on percentage point improvement as this may incentivize bias in the selection of members and inappropriately reward efforts that have minimal actual impact on population-level disparities in care.

The majority of commenters did not support rank orderings and percentiles, while a commenter cautioned that particular care is required with these approaches to avoid unintentional harm and another commenter agreed with CMS's recommendation that many approaches be considered. A commenter stated that rankings, or ordering, particularly when it impacts reimbursement, may lead to unintended consequences specifically when these are in large part due to factors outside the provider's control. These commenters believe that using these approaches will likely defeat the purpose of an evolving disparity effort in a quality program.

Commenters had mixed feedback on the threshold approach. Some commenters supported it because it uses statistical testing as to whether a hospital is significantly better, no different, or worse than a national

threshold or benchmark, while other commenters suggested it will not adequality highlight differences between groups that do not account for the error associated with performance estimates. A commenter stated that this approach may identify differences that are not practically meaningful, and it also places significant burden on CMS to determine an appropriate or acceptable level of performance.

A commenter recommended that CMS prioritize methods for the identification of meaningful performance differences that include a combination of approaches, such as peer grouping, benchmarking, and using a measure of statistical significance.

A commenter noted that benchmarking, depending on how it is applied, may also be effective and that relying on statistical differences is not enough. A commenter noted that with time, and maturity, national or state benchmarking could become a key tool for helping providers understand and contextualize their own performance in relation to that of their peers. A commenter recommended that if benchmarking is pursued, that it not be done using national or state averages, but rather comparing like facilities or communities. Another commenter noted that benchmarking may mask local or regional differences in patient populations and resource access, inadvertently penalizing providers serving communities that are some of the most under-resourced and historically marginalized across the country.

Several commenters suggested that across-hospital comparisons and comparisons of within-hospital results be done individually by hospital types or peer groups, to give more fair comparisons. A commenter suggested that peer hospitals could be identified based on patient demographic profile, payer mix, dual-eligible percentage, geographic location (urban vs. rural), and/or bed size.

Response: We appreciate the feedback and suggestions provided by the commenters regarding the availability of social risk and demographic data for use in stratified reporting, and particularly acknowledge the implications stratification approaches may have on provider responsibility and accountability. We will take commenters' feedback into consideration in future policy development.

Comment: Many commenters provided feedback on the proposed guiding principles for the use and application of the results of disparity measurement on reporting strategies for stratified measure results. In general, commenters supported confidential reporting for a short period, although they provided mixed feedback on the appropriateness of public reporting.

Commenters offered several suggestions concerning whether public reporting occur. Some commenters urged CMS to refrain from public reporting measures with stratified data. A commenter suggested that some measures may be important for internal quality improvement but may not be appropriate for public reporting. Other commenters suggested that stratified measures that contained imputed data, or area-based data, not be publicly reported while others expressed concerns about whether the data would be misunderstood by patients and the public. Some commenters noted that public reporting could lead to unintended consequences, for example, the perpetuation of stereotypes about the type of care provided by the hospital or its providers to certain groups of patients or patient selection bias.

A commenter stated that in its modeling of value incentive programs, it concluded that there is a need for better measures of patient social risk than are currently available. This commenter also recognized that another approach to capture beneficiary social risk would be to use area-level measures of social risk.

A commenter outlined another potential unintended consequence as discouraging more resourced patients from receiving care at hospitals with poor disparity scores, which may not necessarily be indicative of the quality of care the hospital provides. The commenter noted that this could contribute to deepening resource inequity for patients who rely on safety net hospitals. Another commenter requested that CMS provide resources and support to help hospitals and providers interpret, understand, and act upon any stratified data provided to them, which may support less resourced hospitals and discourage this type of gaming.

Other commenters agreed with a period of confidential reporting, followed by public reporting, and offered several suggestions as to when public reporting begin. Several commenters suggested that public reporting not begin until: complete, accurate and up-to-date data become available; there is a review and correction period; disparity reports are validated; or, there are risk adjustments.

Many commenters supported moving to public reporting of stratified measure results. They noted that public reporting enable comparisons of individual providers with state and national averages to give consumers meaningful reference points and that quality improvement activities, through public reporting, would allow patients and their family members to make more informed health care decisions and health care provider choices. A few commenters noted that if information about disparities is made public, health insurance providers and health plans would be better able to understand which health care providers in their networks were taking meaningful action to improve health equity.

Commenters expressed concerns that public reporting, which included demographic data derived using imputed methodology, was less accurate than self-reported data and therefore could lead to measure bias. A commenter expressed concerns regarding the privacy implications under the HIPAA of public disclosure of self-reported data and how it might affect patients' willingness to self-report these data. Other commenters believed that stratified measures not be publicly reported because, in their view, public reporting of stratified measures would not add value for consumers, who generally select providers based on proximity, insurance coverage, provider referral, and recommendations from family and friends, among other criteria.

Response: We appreciate the feedback and suggestions proposed guiding principles for the use and application of the results of disparity measurement on reporting strategies for stratified measure results, including the importance of ensuring that both patients and providers are given the tools and resources to adequately interpret these results. We will take commenters' feedback into consideration in future policy development.

Comment: Many commenters supported CMS's goal of advancing health equity. Many commenters also supported CMS's efforts to measure healthcare disparities and report these results to healthcare providers and to use quality measures stratified by demographic variables and social risk factors as a part of these efforts. Commenters also supported CMS's efforts to improve data collection as a part of its health equity efforts.

Commenters suggested that CMS establish feedback loops to ensure health equity quality measures keep up with evolving practices in the field and measurement science, consider using a Technical Expert Panel or other mechanism to advise it on this process, and partner with other organizations as it continues to refine its principles so

that any unintended consequences of this work are identified and avoided.

A commenter recommended expanding health equity efforts to other settings such as outpatient hospital and ambulatory surgical centers. Commenters also suggested measures be selected and prioritized that: can be impacted by an intervention; protect the safety net; are within the locus of control of the measured entity; minimize burden; and, strike a balance between innovation and feasibility.

Response: We appreciate the general feedback and suggestions provided by the commenters regarding stratified reporting. We are committed to continued transparency in the reporting of performance, particularly with regards to achievement on health equity goals, to providers and to the patients they serve. This commitment extends across hospitals and to all other providers and care settings participating in CMS quality programs. We will take commenters' feedback into consideration in future policy development.

C. Continuing To Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs—Request for Information

In the FY 2022 IPPS/LTCH PPS final rule, we stated the aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs (86 FR 45342). As part of this modernization of our quality measurement enterprise, we issued this RFI to gather broad public input on the transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future notice-and-comment rulemaking. In the FY 2023 IPPS/LTCH PPS proposed rule, we discussed this RFI which contains five parts (87 FR 28486 through 28489):

- *Background.* This part provides an overview of our goals and strategies to achieve digital quality measurement, and notes input and learnings relevant to these goals and strategies.
- *Refined definition of Digital Quality Measures (dQMs).* This part outlines potential revisions for a future definition for dQMs.
- *Data Standardization Activities to Leverage and Advance Standards for Digital Data.* This part discusses data standardization strategies and potential venues for advancing data standardization.
- *Approaches to Achieve FHIR® eCQM Reporting.* This part describes activities we are undertaking and considering to achieve FHIR-based electronic clinical quality measure (eCQM) reporting (for example, via FHIR APIs) as our initial implementation of dQMs.
- *Solicitation of Comments.* This part lists all requests for input included in the sections of this RFI.

1. Background

In the FY 2022 IPPS/LTCH PPS final rule, we noted the continued focus on use of digital data and advancements in technology and technical standards to improve interoperability of healthcare data which creates opportunity to significantly improve our quality measurement systems (86 FR 45342). In a learning health system, standardized and interoperable digital data from a single point of collection can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. We believe data used for quality measurement, as well as these other use cases, be a seamless outgrowth of data generation from routine workflows. Data sharing be standards-based to maximize interoperability, minimize burden, and facilitate the development and use of common tooling across use cases. This approach supports data analysis, rapid-cycle feedback, and quality measurement that are aligned for continuous improvement in patient-centered care.

We are continuing to define how we can leverage existing policy to transform all CMS quality measurement to digital reporting, such as policy finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). In that rule, ONC finalized a ''Standardized API for Patient and Population Services'' certification criterion (45 CFR 170.315(g)(10)) for certified health information technology (IT) requiring the use of FHIR Release 4 and several other implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742). The ONC 21st Century Cures Act final rule (85 FR 25642) also required health IT developers to update their certified health IT to support the United States Core Data for Interoperability (USCDI) standard, Version 1.[396] By aligning technology requirements for payers, healthcare providers, and health IT developers, HHS can advance an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

In the FY 2022 IPPS/LTCH PPS final rule, we outlined actions in four areas to transition to digital quality measures: (1) leverage and advance standards for digital data and obtain all electronic health record (EHR) data required for quality measures via provider FHIR-based application programming interfaces (APIs); (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate (86 FR 45342). The actions are further described in CMS' Digital Quality Measurement Strategic Roadmap available at: *https://ecqi.healthit.gov/dQM.* In this RFI, we focused on data standardization activities related to leveraging and advancing standards for digital data and approaches to transition to FHIR eCQM reporting in the future, as initial steps in our transition to digital quality measurement.

In the FY 2022 IPPS/LTCH PPS final rule, we also stated our goal of moving to digital quality measurement for all CMS quality reporting and value-based purchasing programs (86 FR 45342). In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28487), we further clarified that we plan to transition incrementally, beginning with the uptake of FHIR API technology and shifting to eCQM reporting using FHIR standards as described subsequently in section IX.C.4. of the preamble of the proposed rule. We aim to achieve a quality measurement system fully based on digital measures. The goals of a fully digital measurement system include: Reduced burden of reporting; provision of multi-dimensional data in a timely fashion, rapid feedback, and transparent reporting of quality measures; digital measures leveraged for advanced analytics to define, measure, and predict key quality issues; and quality measures that support development of a learning health system, which uses key data that are also used for care, quality improvement, public health, research, etc.

2. Refined Definition of Digital Quality Measures (dQMs)

In the FY 2022 IPPS/LTCH PPS final rule, we sought to define a dQM as software that processes digital data to produce a measure score or measure scores (86 FR 45342). In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28487), based on feedback regarding

[396] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

confusion by the term ''software,'' we further clarified that dQMs are quality measures, organized as self-contained measure specifications and code packages, that use one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. We continue to note data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, laboratory systems, prescription drug monitoring programs (PDMPs), instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated data such as a home blood pressure monitor, or patient-reported health data), health information exchanges (HIEs) or registries, and other sources. We are currently considering how eCQMs, which use EHR data, can be refined or repackaged to fit within the dQM umbrella. While eCQMs meet the definition for dQMs in many respects, limitations in data standards, requirements, and technology have limited their interoperability. In the current state, there are multiple standards that must be supported (for example, Health Quality Measurement Format (HQMF) [397] and Quality Reporting Document Architecture (QRDA) [398]) for eCQM data collection and reporting. Mapping EHR data can be challenging and burdensome for providers as there is often novel data collection occurring to support quality measurement. For example, eCQMs require steps to map data elements from the EHR to the appropriate format. Future dQMs would leverage interoperability standards to decrease mapping burden and align standards for quality measurement with interoperability standards used in other healthcare exchange methods.

We sought comment on this refined definition of dQMs and feedback on potential considerations or challenges related to non-EHR data sources.

3. Data Standardization Activities To Leverage and Advance Standards for Digital Data

As noted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45342), we are considering implementing eCQM quality reporting via FHIR-based APIs based on standardized, interoperable data. Advancing data standardization is a critical step for this implementation, and for long-term digital measurement strategies. Utilizing standardized data for EHR-based measurement (based on the FHIR standard) and aligning where possible with other interoperability requirements can reduce the data collection burden incurred by providers for the purpose of reporting quality measures and supports achieving the goals of transitioning to a fully digital quality measurement system identified in section IX.C.1. previously, including provision of timely feedback, leveraging the same data for multiple use cases, and contributing to a learning health system.

We intend to utilize standardized data for quality measurement as one use case of digital data in a learning health system. In a learning health system, standardized digital data can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. We believe that standardization across data elements and data models is necessary to ensure data are accessible across use cases and enable the transmission of data through each stage of the health system's learning process. Standardized data and FHIR APIs are important for advancing interoperability; the goal is for data to be sent and received via trusted exchanges, and for patients to have access to their data. Operations activities (for example, prior authorization) are also dependent on standardized, interoperable data. Additionally, standardization is necessary across implementation guides, or rules for how a particular interoperability standard be used,[399] and across value sets that organize the specific terminologies and codes that define clinical concepts.[400]

Commenters on the RFI in the FY 2022 IPPS/LTCH PPS proposed rule encouraged the use of data elements for quality measurement that are consistent with ONC's USCDI standard,[401] where possible. We agree with this approach. To advance the use of standardized data, models, implementation guides, and value sets in quality measurement, we continue to focus on leveraging the interoperability data requirements for standardized APIs in certified health IT, set by the ONC 21st Century Cures Act final rule and any future updates made in rulemaking, as a vehicle to support modernization of CMS quality measure reporting. These API requirements are being implemented as part of a series of updates to certified health IT (85 FR 84825), and include availability of data included in the USCDI via standards-based APIs. In the CY 2021 Physician Fee Schedule final rule, we finalized that eligible clinicians and eligible hospitals and CAHs participating in the Merit-based Incentives Payment System (MIPS) and the Medicare Promoting Interoperability Program, respectively, must transition to use of certified technology updated consistent with the 2015 Edition Cures Update by 2023 (85 FR 84825). We aim to align with these standardized data requirements as the basis for data used in quality measurement.

We are collaborating with federal agencies to define and prioritize additional data standardization needs and develop consensus with federal partners on recommendations for future versions of the USCDI. We are also directly collaborating with ONC to build requirements to support data standardization and alignment with requirements for quality measurement. ONC recently launched the USCDI+ initiative focused on supporting identification and establishment of domain specific datasets that build on the USCDI foundation.[402] A USCDI+ quality measurement domain currently being explored could support defining additional data specifications for quality measurement that harmonize, where possible, with other federal agency data needs and inform supplemental standards necessary to support quality measurement.

We also received feedback on the RFI in the FY 2022 IPPS/LTCH PPS proposed rule that the use of Health Level Seven (HL7®) Implementation Guides are foundational to FHIR measure reporting. To advance implementation of standardized data, we continue to collaborate with consensus standards-setting bodies such as HL7. We are considering how best to leverage existing implementation guides that are routinely updated and maintained by HL7 to define data standards and exchange mechanisms for FHIR-based dQMs, in a fashion that supports the learning health system and alignment across use cases, including the following existing HL7 Implementation Guides:

- US Core Implementation Guide; [403]

[397] *https://www.hl7.org/implement/standards/product_brief.cfm?product_id=97.*

[398] *https://ecqi.healthit.gov/qrda.*

[399] Resource Implementation Guide—Content. Available at: *https://www.hl7.org/fhir/implementationguide.html.*

[400] National Library of Medicine, Value Set Authority Center. Available at: *https://vsac.nlm.nih.gov/.*

[401] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[402] USCDI+. Available at: *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

[403] HL7 FHIR US Core Implementation Guide. Available at: *http://hl7.org/fhir/us/core/.*

- Quality Improvement Core (QI Core) Implementation Guide; [404]
- Data Exchange for Quality Measures (DEQM) Implementation Guide; [405] and
- Quality Measure (QM) Implementation Guide.[406]

We are also considering what, if any, additional CMS-specific implementation guides may be necessary to support future digital quality measurement such as guidance on aggregation mechanisms for reporting.

We recognize the importance of considering how implementation guides used across quality measurement and other use cases (for example, public health reporting, clinical decision support) work together to support a learning health system. For example, the Clinical Guidelines (CPG) Implementation Guide [407] connects computable guidelines, clinical decision support, quality reporting, and case reporting. The mechanisms for reporting across use cases are also critical to consider, as each time a different mechanism for reporting is needed across different use cases, it creates more burden. We are collaborating closely with federal partners, such as the Centers for Disease Control and Prevention (CDC), to align where possible.

We believe developing appropriately defined implementation guides will be a key component of supporting standardized FHIR APIs that enable access to standardized data elements for particular use cases, such as quality measurement.

We sought comment on the specific Implementation Guides noted previously, additional implementation guides to consider, and other data and reporting components (for example, data vocabulary/terminology, alignment with other types of reporting) where standardization may be considered to advance data standardization for a learning health system.

4. Approaches to Achieve FHIR eCQM Reporting

We previously noted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45342) activities we are conducting to begin structuring and reporting eCQMs using FHIR. eCQMs are a subset of dQMs. We consider the transition to FHIR-based eCQM reporting the first step to dQM reporting, and a potential model for how future digital reporting can occur.

To support the transition, we continue to undertake and consider activities necessary for reporting of FHIR-based eCQMs and future dQMs:

- In the near term, we plan to continue to convert current Quality Data Model (QDM)-based eCQMs to the FHIR standard and test the implementation of measures respecified to FHIR and submission of data elements represented in FHIR through ongoing HL7 Connectathons.
- In the near term, we also plan to develop a unified CMS FHIR receiving system. This system would allow for a singular point of data receipt to be used for quality reporting requirements, and modernization of programmatic data receiving systems to leverage opportunities related to digital data.
- We are committed to working with implementers and partners to optimize interoperable data exchange to support FHIR-based eCQM reporting (for example, via FHIR APIs) and eventually other dQMs, while ensuring solutions and implementations that require patients to engage with technology that also support health equity.
- In the near term, we plan to identify opportunities for the public to provide feedback on FHIR-based measure specifications prior to implementation, such as during measure development/conversion activities.
- We also plan to identify opportunities for collaboration with vendors and implementers via systems testing of FHIR-based eCQM reporting to ensure involvement in systems development.
- Finally, we are exploring venues for continued feedback on CMS future measurement direction and data aggregation approaches in anticipation of FHIR-based API reporting of eCQMs.
- To support both near term FHIR-based eCQMs and other future dQMs, as noted in section IX.C.3., we intend to continue engaging with standards development organizations to advance and maintain implementation guides to support the FHIR standard and API reporting of quality measures.
- We also anticipate that prior to the implementation of any mandatory FHIR-based eCQM reporting requirements within our quality programs, it would be necessary to undertake voluntary reporting of FHIR-based eCQMs to allow time to learn and enhance systems and processes, both internally and among providers and vendors.

We also continue to consider how best to leverage the FHIR API technology implemented to meet ONC's interoperability requirements to access and electronically transmit interoperable data for quality measurement. Based on feedback on the FY 2022 IPPS/LTCH PPS proposed rule RFI, many supported the use of FHIR APIs, while others expressed concern around infrastructure readiness. We continue to explore how to leverage FHIR APIs to decrease reporting burden and support implementor readiness. We sought comment on approaches to optimize data flows for quality measurement to retrieve data from EHRs via FHIR APIs, and to combine data needed for measure score calculation for measures that require aggregating data across multiple providers (for example, risk-adjusted outcome measures) and multiple data sources (for example, hybrid claims-EHR measures). We were interested in data flows that support using the same data for measurement and to provide feedback to providers at multiple levels of accountability, such as at the individual clinician, group, accountable care organization and health plan levels, as are used for patient care and other use cases (for example, public health reporting).

We sought comment on additional venues to engage with implementors during the transition to digital quality measurement, and other critical considerations during the transition. We also sought comment on data flow options to support FHIR-based eCQM reporting.

5. Solicitation of Comments

As noted previously, we sought input on the following:

- Refined potential future Definition of dQMs. We sought feedback on the following as described in section IX.C.2.:

++ Do you have feedback on the potential refined definition of digital quality measures (dQMs)?

++ Do you have feedback on potential considerations or challenges related to non-EHR data sources?

- Data Standardization Activities to Leverage and Advance Standards for Digital Data. We sought feedback on the following as described in section IX.C.3.:

++ Do you have feedback on the specific implementation guides we are considering, additional FHIR implementation guides we consider, or other data and reporting components where standardization be considered to advance data standardization for a learning health system?

- Approaches to Achieve FHIR eCQM Reporting. We sought feedback on the following as described in section IX.C.4.:

[404] HL7 FHIR QI Core Implementation Guide. Available at: *http://hl7.org/fhir/us/qicore/*.

[405] HL7 Data Exchange For Quality Measures. Available at: *http://hl7.org/fhir/us/davinci-deqm/*.

[406] HL7 Quality Measure Implementation Guide. Available at: *http://hl7.org/fhir/us/cqfmeasures/*.

[407] HL7 FHIR Clinical Guidelines Implementation Guide. Available at: *http://hl7.org/fhir/uv/cpg/*.

++ Are there additional venues to engage with implementors during the transition to digital quality measurement?

++ What data flow options we consider for FHIR-based eCQM reporting, including retrieving data from EHRs via FHIR APIs and other mechanisms?

++ Are there other critical considerations during the transition?

We received several comments on these topics.

Comment: There was widespread support among commenters for CMS' efforts to transition to digital quality measurement and support for leveraging the FHIR standard and FHIR APIs. A couple of commenters pointed out that improved electronic health record (EHR) interoperability for the exchange and use of electronic health data holds great promise to not only improve quality measurement and patient outcomes, but also to reduce burden on providers. A commenter noted that dQMs are a critical component of a fully interoperable learning health system that generates knowledge beyond the quality reporting use case, and suggested CMS make this clear in its transition plans. A commenter supported CMS's iterative approach to transition quality reporting programs to the use of dQMs and the FHIR standard. Another commenter noted that leveraging EHRs for dQM must not interfere, delay, or hinder patient care. While there was general support for use of the FHIR standard, a few commenters noted the standard was not yet fully mature, and a commenter recommended allowing for flexibility in standards used, focusing on a set of standards rather than using only FHIR. Additionally, a commenter stated that the FHIR standard is not broad enough to support all potential use cases, and that some EHR data does not map to the standard. The commenter recommended CMS work with ONC to advance the adoption and consistent implementation of data and interoperability standards, so that provider data collection and reporting requirements are enabled by health IT.

Commenters differed in their input on the time to transition to dQMs. Although CMS did not indicate transition by 2025 in the RFI in the FY 2023 IPPS/LTCH PPS proposed rule, some commenters noted feasibility to transition by 2025, whereas some expressed concerns regarding the timeline for dQM rollout. Some commenters noted it would be feasible to submit EHR data by 2025, and many commenters agreed with beginning the transition with EHR-based APIs and expand into other data sources, as technology development and testing allows. A commenter noted if the data submission requirements extend beyond EHR data, there would need to be changes to infrastructure which would be burdensome. Many commenters requested the transition be delayed beyond 2025, until the technology evolves further. A commenter suggested CMS account for at least two to three years to accommodate EHR vendor development, budget considerations, and testing, implementation, and validation activities as it transitions to dQMs.

Another commenter recommended CMS provide at least three to four years between finalizing any policies around the transition timeline to requiring FHIR-based API functionality for health IT products/systems that are not already going through ONC's Health IT Certification Program (Certification Program). A few commenters requested CMS provide transparency and more detailed plans about the transition to dQMs, or suggested CMS be flexible with the deadline for launching dQMs.

Several commenters recommended CMS use the Trusted Exchange Framework and Common Agreement (TEFCA) or CareQuality, which are interoperability frameworks, through the beginning of this transition. The commenters suggested that CMS move ahead in this transition using data tools that CMS already has access to and are already in use. They also requested CMS release more information regarding the current system capabilities. Conversely, a commenter suggested that CMS not use preexisting tools, but instead use new and innovative data tools.

Several commenters stated that while the transition to dQMs occurs, it is imperative that quality measurement continues, and that quality of care is not affected by the transition. A commenter stated that there are still current eCQM operational challenges that must be addressed prior to the transition to dQMs. Commenters also questioned which dQMs would be implemented first. Several commenters suggested dQMs rolled out first be clinically relevant and useful.

Response: We appreciate all of the comments on and interest in this topic. This input is very valuable in our continuing planning for the transition to the digital quality measurement in CMS quality reporting and value-based purchasing programs. We continue to take all input into account as we develop future regulatory proposals for our digital quality measurement transition efforts.

Comment: Many commenters supported the refined dQM definition noting it provides a ''good overview of the intent behind dQMs'' and it captures ''the full range of evolving healthcare information sources.'' Some commenters noted the definition is still too broad and requested clarification on components of the definition and examples of dQMs. A commenter encouraged CMS to continue with refinement of its dQMs definition and set clear, specific parameters for what it hopes to achieve and what it expects of hospitals. A commenter requested CMS clarify what would make a successful dQM interoperable or conversely not interoperable. Another commenter noted that establishing dQMs as free-standing software, as defined, may disincentivize the use of clinical data registries, which add additional value to the healthcare ecosystem.

A commenter stated that not all data sources identified for use in dQMs are ready for inclusion in quality measurement. As an example, the commenter stated that wearable devices and patient-generated health data have not been vetted as valid and reliable interoperable data sources or as usable data for clinical quality improvement and assessment, and wearable devices, such as smartwatches and fitness trackers are not universally adopted and may introduce bias or inequities. Another commenter suggested the definition include the potential for dQMs to be developed in a way that allows their components to support a variety of use cases, such as decision support and quality improvement.

Several commenters noted the ambiguity around eCQMs compared to dQMs and requested for further distinction. A commenter requested clarification as to whether eCQMs will be separate and distinct from dQMs or incorporated into dQMs. Some commenters expressed concern around the introduction of new eCQMs if CMS is transitioning to dQMs given the resources and investments necessary for supporting new measures.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs. We will continue to take all comments into account as we refine the digital quality measure definition.

Comment: Commenters were divided on the use of non-EHR data sources for dQMs. Several commenters indicated non-EHR data sources could enhance the accuracy and completeness of data

to determine hospital quality performance. A commenter encouraged CMS to continue to leverage a broad set of data sources for digital quality measurement rather than relying solely on EHR-derived, standardized data, which would limit the completeness, accuracy, and timeliness of the data used to determine hospital quality performance. Commenters recommended CMS align with other federal initiatives such as the FDA's use of non-EHR data sources such as patient-generated health data. Other commenters expressed concern that hospitals and clinicians may be unable to calculate or understand their performance internally if other data sources are incorporated into dQMs. Some commenters stated that because non-EHR data are often not standardized or not yet standardized, non-EHR data sources could increase mapping burden, and that platforms are not yet available to support electronic capture, extraction, and access from non-EHR data sources. A commenter noted CMS would need to address unintended consequences of inadequate data quality for non-EHR data sources. Some commenters noted that patient matching must be considered when aggregating or combining data from disparate systems or sources. A commenter suggested that CMS' initial focus of dQMs remain on measures that emphasize the use of data available in EHRs. Another commenter requested CMS to provide specific details for how hospitals are expected to make data from non-EHR sources available. A commenter noted that other health IT are not required to certify to ONC's Health IT Certification program and that there are no FHIR-based API requirements for other health IT, which poses challenges for integrating non-EHR data sources. The commenter suggested CMS will need to establish specific requirements on its own, or in collaboration with ONC, to require other health IT systems/products to develop and maintain FHIR-based APIs that CMS could leverage to query the data necessary for dQMs.

Several commenters noted additional burden when considering non-EHR data for interoperability and data standardization. A couple of commenters noted requiring data capture beyond what clinicians document in their typical workflows would add development and documentation burden and require infrastructure changes. A commenter expressed concern with CMS' vision for an ecosystem with a broad set of data sources when the calculation of existing quality measures using data from source EHRs still uncovers gaps in data which hinder quality measure calculations.

A few commenters noted that as CMS moves toward dQMs that use data sources across various non-EHR health IT, that EHRs not be the data aggregator or be expected to capture, store, and share information that would not be routinely captured in an EHR. Commenters recommended CMS aim to obtain data from the data's source system when possible.

Commenters requested more specific transition plans for the incorporation of non-EHR data sources into dQMs, and a commenter strongly suggested CMS consider how the use of non-EHR data would impact dQM development and timelines.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs. We will continue to take all comments into account as we refine the dQM definition and consider the use of non-EHR data sources for digital quality measurement.

Comment: Many commenters expressed support for the implementation guides CMS is considering using for digital quality measurement, including the Quality Improvement (QI) Core and the Data Exchange for Quality Measures (DEQM) Implementation Guides. Several commenters also specifically supported the use of the Da Vinci Implementation Guide and the C–CDA Implementation Guide. A commenter also supported standardization across implementation guides as CMS outlined in this RFI. Commenters also recommended CMS consider the following additional IGs: the Clinical Guidelines (CPG) Implementation Guide, the FHIR Bulk Data Access Implementation Guide, Carequality's FHIR-Based Exchange Implementation Guide, and specialty-specific implementation guides. A commenter noted it could provide more effective feedback when CMS clarifies what data elements and APIs the agency intends to use, and from where they intend to access data. The commenter provided the example that if CMS would like to access health information typically stored in a financial or billing product along with clinical health information for a dQM, the implementation guidance would likely be different than if CMS is looking to use clinical data only for a dQM.

Several commenters encouraged CMS to continue testing and validating the implementation guides, recommending implementation guides be fully developed and sufficiently tested for successful implementation of truly interoperable sharing and transparency. Several commenters recommended that implementation guides be mature, defined by a commenter as broad adoption and completion of the balloting process. A commenter recommended CMS seek input from stakeholders through Connectathons and public comment to further refine the implementation guides.

Several commenters expressed concerns that alignment, testing, and maturity of the standards need to be completed before the implementation guides can be used for CMS programs. One of these commenters specifically noted alignment of definitions of common quality measurement concepts across implementation guides still must be accomplished. A commenter noted they could not provide feedback on the specific implementation guides until CMS communicates decisions on what dQMs CMS intends to implement, what data elements and APIs CMS intends to use, and where CMS is intending to pull the data from. Several commenters also encouraged CMS to provide implementers sufficient time after implementation guides are completed before initiating program requirements.

Several commenters expressed concerns about the limitations of the currently available implementation guides, such as the DEQM defining methods for exchange at the individual resource or data element level, while data are currently exchanged at the measure document level and enabling EHRs to push quality reporting data via FHIR APIs only at the aggregate level, but not at the patient level. Another commenter expressed the need for specialty-specific implementation guides.

Several commenters recommended CMS develop further implementation guidance, including clarifying which exchange methods will be required for use in FHIR eCQM reporting, aggregation of data across interoperable systems for the purpose of quality measurement, and methods for collection of social determinants of health data for measure stratification and risk adjustment. A commenter suggested bucketing guidance into two categories: (1) content or context IGs (such as measures specifications) and (2) operational IGs (such as for data aggregation or CMS reporting). Regarding aggregation guidance, commenters noted the importance of aggregation activities including normalizing, standardizing, and quality assurance activities via valid methods.

Some commenters also noted that some data, for example EHR notes, are free text and in their current state cannot be extrapolated and therefore require manual abstraction. An additional commenter recommended optimizing these resources for better care that is safe, affordable, and equitable, prioritizing which IGs are being built to align with the goals for quality improvement programs. A commenter noted that in terms of guidelines and standardization of data within the implementation guides, CMS avoid a ''one size fits all'' approach. Another commenter suggested the importance of consistency of data definitions, as they believe this is fundamentally critical to ensure analysis and interpretations can be applied across the healthcare system.

Commenters also supported alignment with ONC's USCDI and development of USCDI+ for quality measurement. A commenter specifically supported replacing the Common Clinical Data Set (CCDS) for information exchange with the more robust USCDI. These commenters noted that the USCDI may not include all data elements necessary for quality measurement, and that the USCDI+ must still be defined. Therefore, additional standards may still be required to support quality measurement. A commenter suggested the USCDI+ be incorporated into certified EHR technology requirements to support implementation. Another commenter noted the importance of federal and commercial alignment on data needs included in USCDI and USCDI+. Another commenter pointed out that a holistic approach is needed for data standards whereby standards are developed and adopted for use across care settings. The commenter added that there are at present a limited number of common data elements across inpatient, outpatient, and post-acute care; however, these elements could serve as a starting point for cross-continuum patient assessment.

Response: We appreciate all of the comments and suggestions on this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs underpinned by data standardization activities. We will continue to take all comments into account as we refine implementation guides and additional guidance for dQM reporting.

Comment: Several commenters provided input on additional venues to engage with implementors and other stakeholders during the transition to digital quality measurement. Several commenters requested CMS continue to solicit feedback from the public and other agencies on the transition to dQMs. Many commenters suggested CMS continue to participate in and host events, such as Connectathons, conferences, webinars, and the CMS Quality Conference to further explain CMS' plans to advance digital quality measures and to solicit feedback.

Commenters also suggested CMS collaborate with and solicit feedback from a variety of other stakeholders including, but not limited to: the Core Quality Measures Collaborative (CQMC), the National Quality Forum (NQF), the National Committee for Quality Assurance (NCQA), technical expert panels, health insurers, clinicians, EHR Association, hospitals, clinical registries, and health IT developers. Commenters also suggested CMS work with health information exchanges (HIEs) and regional health information exchanges (RHIEs), which have experience with data flow options and dQM data collection and exchange. Some commenters also offered to provide CMS with additional feedback as the agency works on transitioning to dQMs.

Commenters also recommended CMS work with ONC to update certification criteria if FHIR-based dQMs require the implementation of additional FHIR APIs. A commenter expressed concern that development and documentation burden would increase, if CMS would require data capture beyond what clinicians document in their typical workflows.

Regarding testing of dQMs, several commenters recommended CMS conduct sufficient large-scale testing and consult with multi-stakeholder groups such as the Health Information Technology Advisory Committee (HITAC) and NQF prior to wide-spread adoption. Several commenters also noted the utility of Connectathons for testing.

Response: We thank commenters for their suggestions for soliciting feedback. CMS will continue to solicit feedback from the implementers and other stakeholders throughout the transition planning and implementation of dQMs.

Comment: Regarding data flow options, several commenters supported CMS' overall direction towards using Clinical Quality Language (CQL), FHIR, and FHIR-based APIs for digital quality measurement, as common language and data source availability would promote data consistency across health IT systems.

Several commenters expressed concerns and suggestions regarding data privacy and security. Some commenters expressed concerns regarding privacy of the non-EHR data sources, noting that non-EHR data sources do not have to abide by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and expressed concerns about the security of Protected Health Information (PHI) in non-EHR environments. Commenters also expressed concerns about privacy of data accessed via FHIR APIs. A commenter requested clarification about whether FHIR receiving systems will hold PHI, and if so for how long and how PHI would be secured. Commenters inquired whether patients would have the ability to opt-out of their information being transferred. Another commenter expressed concern about private information being shared with entities that are not covered by HIPAA and requested CMS work with Congress to fill the gap in the national privacy framework by developing robust federal privacy laws and regulations applicable to organizations that obtain healthcare data but are not subject to HIPAA. In addition, the commenter suggested HHS and the Federal Trade Commission (FTC) work together to find an effective stop-gap measure that can be implemented to protect potentially personally identifiable information that could be shared via APIs.

While several commenters supported CMS's vision in accelerating the use of the FHIR standard and FHIR APIs to improve the exchange of health information to improve patient satisfaction and care, some commenters noted they do not themselves guarantee data quality, accuracy, or completeness. Commenters suggested CMS clarify how data integrity would be maintained for CMS dQM reporting and consider unintended consequences if the data quality is inadequate. A commenter noted using existing FHIR US Core-based APIs may not be an ideal approach for CMS dQM reporting, depending on the volume of data being considered and the frequency of data access. The commenter also stated that the FHIR resources needed to calculate dQMs may go beyond those available through FHIR US Core-based APIs. Another commenter stated concern about the variation of FHIR versions, and lack of version requirements. A commenter noted there are limitations on a provider's ability to connect to certain applications to submit data with multiple versions of FHIR and no version requirements.

A few commenters expressed concern that API data providers, healthcare systems and provider practices may be unfairly burdened by fees and costs incurred from API technology providers. A commenter expressed concern that

payers or providers could be required to purchase certain software or be forced to pay to join registries or HIEs. A commenter expressed an additional concern that the API implementation costs would be shifted onto healthcare systems and physician practices, which could have a significant deleterious effect on smaller practices.

Several commenters provided input on other considerations.

A couple of commenters provided input on CMS' vision for the FHIR-based measure calculation tool, described in CMS's Digital Quality Measurement Strategic Roadmap, although CMS did not request comment on the tool in this RFI. CMS previously requested comment on the tool in the FY 2022 IPPS/LTCH PPS proposed rule. A commenter requested clarification about whether measure calculation tools that would be created by CMS would enable real-time performance monitoring and about the frequency of measure calculation tool queries. The same commenter noted validation would need to be redone to verify that accurate measure outcomes were calculated by a measure calculation tool after measures are expressed in FHIR. Another commenter recognized the promise of an end-to-end measure calculation tool for distributing digital quality measures from a measure calculation tool to end users.

A commenter requested CMS provide information on the CMS FHIR receiving system to be used for digital quality measurement. The commenter requested clarification on the CMS FHIR receiving system's attributes including how the system would know which APIs to query for which information, and if the CMS FHIR receiving system would rely on querying APIs or publication/subscription functionality not currently required by ONC or CMS.

Many commenters raised concern with burden. Several commenters noted CMS consider the burden of transitioning to dQMs and ensure dQMs do not increase overall quality reporting burden. A commenter acknowledged the potential of dQMs as an end-to-end reporting solution and stated their belief that dQMs could enable a true learning health system in which real-time feedback from dQMs could be shared with providers for clinical decision support at the point-of-care. Commenters noted that while FHIR-based quality collection and reporting may potentially reduce the effort involved in measurement in the longer term, there are several precursor steps that need to be taken as setting up this capability will be burdensome for health IT vendors and providers.

As noted previously, several commenters provided input on the timeline for transition and timeline feasibility. Commenters requested clarity from CMS on the transition timelines, including timelines for the phase-out of or addition of eCQMs, the use of USCDI+, the use of FHIR-based API, and when CMS would publish the required data elements and specifications for required dQMs.

Several commenters noted the timeline to transition to dQMs is the biggest challenge and that period would significantly increase burden on providers, with even greater concerns noted for LTCHs and small rural hospitals. Commenters noted the long-term benefit of the transition to dQMs and FHIR however acknowledged the up-front burden. While beyond the scope of concern for the Hospital IQR Program or this RFI, commenters expressed similar concerns for other Medicare payment systems and other provider types that use non-certified health IT that also would have little historical reason for adoption of FHIR-based APIs. These commenters stated that if CMS is considering adoption of dQMs for the quality reporting programs for post-acute care, home health or other provider types, they believe it will be challenging to incentivize these other provider types to adopt updates to their health IT and to push health IT vendors and developers to develop those capabilities.

Many commenters also noted data mapping challenges and associated burden. Some commenters noted they do not anticipate less mapping burden than current state with the transition to FHIR. Other commenters noted that data mapping guidance is necessary to ensure that the underlying data being accessed via FHIR APIs is accurate, valid, and consistent across providers. A commenter suggested CMS publish a deliberative roadmap that focuses on how source systems can generate the relevant source data set into an agreed-upon FHIR-based format mapping to the source health IT's internal data structures, before attempting to access such data directly through data element level FHIR-based APIs. The commenter noted the approach would also enable more focus initially on data mapping, quality, and completeness, and on patient matching across health IT to ensure data is properly correlated for dQMs beyond EHRs.

Some commenters identified FHIR bulk data as a critical component to using FHIR for eCQMs. Commenters noted bulk FHIR transactions simplify and speed transmission and reduce risk of overtaxing source APIs depending on the volume of data and frequency of access required for dQMs. A few commenters noted bulk FHIR would be required for providers to support FHIR implementation.

A few commenters suggested the current method of pulling and submitting files yearly to the HQR portal is burdensome and often encounters issues with data validation. The commenters noted that a direct connection for data submission and validation would reduce burden, because providers would not need to do anything more than initiate data retrieval and authorize data submission once it has been processed. Several commenters explained that due to the burden this transition would put on care facilities, CMS provide financial, technical, and educational support to these facilities during the transition. Commenters also stated that patient data may not be complete until weeks after the patient encounter, and therefore providers be able to resubmit data for calculations at any point.

A few commenters requested CMS consider mechanisms that would provide resource support to assist and incentives for FHIR eCQM reporting. A commenter noted resource support is especially important for providers who care for underserved and vulnerable populations to ensure all providers can successfully transition to FHIR-based eCQM reporting and that no providers are left behind. A commenter suggested ensuring availability of free education sessions on FHIR-based digital quality measure development, and the provision of user-friendly measure authoring and testing tools. Another commenter suggested monetary incentives to participating in dQM testing.

A commenter recommended participation in standards development processes will continue to provide CMS with the best channels to engage with the health IT developer community during the transition to digital quality measurement. The commenter noted the processes used in standards development give developers an opportunity to provide technical feedback on implementation guides based on their knowledge of how hospitals and clinicians use their software and their experience supporting users' participation in quality reporting programs. The commenter recommended CMS also provide developers access to test submission portals and other testing tools, even if the developer does not submit on behalf of its clients, because testing tools will allow developers to validate that data captured during

clinical workflows is accurately retrieved via FHIR APIs when used for quality reporting. The commenter stated that FHIR-based eCQM reporting will need to support push flows for data correction and revision because hospitals and clinicians may not finalize the clinical or billing documentation for an encounter until weeks after discharge. If the measure calculation tool has already retrieved data for that encounter, hospitals will need a way to re-trigger retrieval so that revised/final data is reflected in the measure outcome calculation. The commenter expressed concern that the DEQM Implementation Guide enables EHRs to push quality reporting data via FHIR APIs, but only at the aggregate level, meanwhile pushing patient level quality reporting outcomes would be required to reconcile discrepancies between quality measure reports before and after revisions took place.

Several commenters recommended real-time, bi-directional data exchange between organizations and CMS, and across the healthcare system, to increase the value of this effort to patients and providers. Commenters noted that data collected and analyzed for dQMs could provide significant benefit for clinical decision support, shared and coordinated care across providers and facilities, and increased ability to track patients' outcomes. A commenter recommended that if dQM calculation is conducted outside of the EHR, it will be essential for those tools to engage in bi-directional data exchange with EHRs to allow users to have actionable insight into their quality measure performance. A commenter emphasized the need for bi-directional exchange of SDOH data with all members of the care team in real-time to support communication around the patients' goals and enable high-quality care for all patients. A commenter questioned whether the measure calculation tools introduced in CMS's Digital Quality Measurement Strategic Roadmap would enable real-time performance monitoring for currently admitted patients.

Response: We appreciate all of the comments on and interest in this topic. This input is very valuable in our continuing planning for the transition to the digital quality measurement in CMS quality reporting and value-based purchasing programs. We continue to take all input into account as we develop future regulatory proposals for our digital quality measurement transition efforts.

D. Advancing the Trusted Exchange Framework and Common Agreement—Request for Information

Section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, amended section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj–11(c)), and required HHS to take steps to advance interoperability for the purposes of ensuring full network-to-network exchange of health information. Specifically, Congress directed the National Coordinator to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' Since the enactment of the 21st Century Cures Act, HHS has pursued development of a Trusted Exchange Framework and Common Agreement (TEFCA). ONC's goals for TEFCA are as follows:

Goal 1: Establish a universal policy and technical floor for nationwide interoperability.

Goal 2: Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.

Goal 3: Enable individuals to gather their health care information.[408]

On January 18, 2022, ONC announced a significant TEFCA milestone by releasing the Trusted Exchange Framework [409] and Common Agreement Version 1.[410] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement for Nationwide Health Information Interoperability Version 1 (also referred to as Common Agreement) is a contract that advances those principles. The Common Agreement and the incorporated by reference Qualified Health Information Network (QHIN) Technical Framework Version 1 (QTF) [411] establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other, all under commonly agreed to terms. The Common Agreement is a legal contract that QHINs [412] sign with the ONC Recognized Coordinating Entity (RCE),[413] a private-sector entity that implements the Common Agreement and ensures QHINs comply with its terms.

[408] See *https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch*.

[409] Trusted Exchange Framework (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf*.

[410] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

[411] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf*.

[412] The Common Agreement defines a QHIN as ''to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-*.

[413] In August 2019, ONC awarded a cooperative agreement to The Sequoia Project to serve as the initial RCE. The RCE will operationalize and enforce the Common Agreement, oversee QHIN-facilitated network operations, and ensure compliance by participating QHINs. The RCE will also engage stakeholders to create a roadmap for expanding interoperability over time. *See* ONC Awards The Sequoia Project a Cooperative Agreement for the Trusted Exchange Framework and Common Agreement to Support Advancing Nationwide Interoperability of Electronic Health Information (September 3, 2019), *https://sequoiaproject.org/onc-awards-the-sequoia-project-a-cooperative-agreement-for-the-trusted-exchange-framework-and-common-agreement-to-support-advancing-nationwide-interoperability-of-electronic-health-information*.

The technical and policy architecture of how exchange occurs under TEFCA follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at those different levels, such as health information networks, care practices, hospitals, public health agencies, and Individual Access Services (IAS) [414] Providers.[415] QHINs connect directly to each other to facilitate nationwide interoperability, and each QHIN can connect Participants, which can connect Subparticipants.[416] Compared to most nationwide exchange today, the Common Agreement includes an expanded set of Exchange Purposes beyond Treatment to include Individual Access Services, Payment, Health Care Operations, Public Health, and Government Benefits Determination [417]—all built upon common technical and policy requirements to meet key needs of the U.S. health care system. This flexible structure allows stakeholders to participate in the way that makes most sense for them, while supporting simplified, seamless exchange.

The QTF,[418] which was developed and released by the RCE, describes the functional and technical requirements that a Health Information Network (HIN) [419] must fulfill to serve as a QHIN under the Common Agreement. The QTF specifies the technical underpinnings for QHIN-to-QHIN exchange and certain other responsibilities described in the Common Agreement. The technical and functional requirements described in the QTF enable different types of information exchange, including querying and message delivery across participating entities.

In 2022, prospective QHINs are anticipated to begin signing the Common Agreement and applying for designation. The RCE will then begin onboarding and designating QHINs to share information. In 2023, HHS expects stakeholders across the care continuum to have increasing opportunities to enable exchange under TEFCA. Specifically, this would mean such stakeholders would be: (1) signatories to either the Common Agreement or an agreement that meets the flow-down requirements of the Common Agreement (called a Framework Agreement [420] under the Common Agreement), (2) in good standing (that is, not suspended) under that agreement, and (3) enabling secure, bi-directional exchange of information to occur, in production. TEFCA is expected to give individuals and entities easier, more efficient, access to more health information while requiring strong privacy and security protections.

We believe that exchange of health information enabled by the Common Agreement can advance CMS policy and program objectives related to care coordination, cost efficiency, and patient-centeredness in a variety of ways. We also believe that CMS policy and programs can help to accelerate nationwide connectivity through TEFCA by health care providers as well as other stakeholders.

We are considering other ways that available CMS policy and program levers can advance information exchange under TEFCA. For instance, similar to the proposal in the current rule, there may be opportunities for CMS to incentivize exchange under TEFCA through other programs that incentivize high quality care, or through program features in value-based payment models that encourage certain activities that can improve care delivery.

In addition to programs focused on providers, we are interested in opportunities to encourage exchange under TEFCA through CMS regulations for certain health care payers, including Medicare Advantage, Medicaid Managed Care, and CHIP issuers. For instance, we believe there may be opportunities to encourage information exchange under TEFCA to support recently finalized requirements for these payers to make information available to patients and to make patient information available to other payers as beneficiaries transition between plans in the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers'' final rule (85 FR 25510). Finally, we are considering future opportunities to encourage information exchange under TEFCA for payment and operations activities such as submission of clinical documentation to support claims adjudication and prior authorization processes.

We are requesting input from the public on the ideas described previously and related concepts for future exploration, as well as the following questions:

- What are the most important use cases for different stakeholder groups that could be enabled through widespread information exchange under TEFCA? What key benefits would be associated with effectively implementing these use cases, such as improved care coordination, reduced burden, or greater efficiency in care delivery?
- What are key ways that the capabilities of TEFCA can help to advance the goals of CMS programs? Should CMS explore policy and program mechanisms to encourage exchange between different stakeholders, including those in rural areas, under TEFCA? In addition to the ideas discussed previously, are there other programs CMS should consider in

[414] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[415] The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[416] For the Common Agreement definitions of QHIN, Participant, and Subparticipant, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 8–12 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[417] For the Common Agreement definitions of Payment, Health Care Operations, Public Health, and Government Benefits Determination, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6–10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[418] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[419] ''Health Information Network'' under TEFCA has the meaning assigned to the term ''Health Information Network or Health Information Exchange'' in the information blocking regulations at 45 CFR 171.102.

[420] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' See Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

order to advance exchange under TEFCA?

- How should CMS approach incentivizing or encouraging information exchange under TEFCA through CMS programs? Under what conditions would it be appropriate to require information exchange under TEFCA by stakeholders for specific use cases?
- What concerns do commenters have about enabling exchange under TEFCA? Could enabling exchange under TEFCA increase burden for some stakeholders? Are there other financial or technical barriers to enabling exchange under TEFCA? If so, what could CMS do to reduce these barriers?

Comment: We received a wide range of comments on this request for information. Many did not recommend requiring TEFCA participation at this time. Some stated that there was confusion about TEFCA in the provider community. A commenter stated that there are difficulties in managing readmissions management under TEFCA that would create productivity decreases and recommended the creation of TECFA billing codes so that hospitals can be compensated. Many commenters raised concerns about the costs associated with participation noting that the costs may be a barrier for many health care providers.

A commenter stated that data sharing for purposes of use beyond medical treatment holds tremendous possibility for advancing the goals of CMS programs and healthcare delivery. Others requested that we provide additional education on the benefits of TEFCA and why it remains essential when there are others ways to accomplish the objective of exchanging information. Another commenter suggested that CMS align any TEFCA Use Cases with the required Exchange Purposes: Treatment; Payment; Health Care Operations; Public Health; Benefits Determination; and Individual Access Services (IAS).

Response: We appreciate the feedback and suggestions provided by the commenters regarding TEFCA. We plan to share all the input with ONC and will take commenters' feedback into consideration in future policy development.

E. Hospital Inpatient Quality Reporting (IQR) Program

1. Background and History of the Hospital IQR Program

Through the Hospital IQR Program, we strive to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians by using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across HHS, we believe the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves.

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. The adoption of widely agreed upon quality and cost measures supports this effort. We work with relevant stakeholders to define measures in almost every care setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess clinical processes, patient safety and adverse events, patient experiences with care, care coordination, and clinical outcomes, as well as cost of care. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the following final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861);
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181);
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653);
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959); and
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426).

We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless a different or more limited time period is proposed and finalized. Measures are also retained unless we propose to remove, suspend, or replace the measures. We did not propose any changes to these policies in the proposed rule.

3. Removal Factors for Hospital IQR Program Measures

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal factors. We did not propose any changes to these policies in the proposed rule.

4. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the previous considerations we have used to expand and update quality measures under the Hospital IQR Program. We also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), in which we describe the Meaningful Measures Framework, our objectives under this Framework for quality measurement, and the quality topics that we have identified as high-impact measurement areas that are relevant and meaningful to both patients and providers. In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements (we note that Meaningful Measures 2.0 is still under development).[421] We did not propose

[421] Centers for Medicare and Medicaid Services. (2021). Meaningful Measures 2.0: Moving from

any changes to these policies in the proposed rule.

We also note that the Hospital IQR Program must first adopt measures and publicly report them on the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*, or its successor website, for at least one year before the Hospital Value-Based Purchasing (VBP) Program is able to adopt them. We view the value-based purchasing programs, including the Hospital VBP Program, as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries.

5. New Measures for the Hospital IQR Program Measure Set

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28491 through 29535), we proposed to adopt 10 new measures, including four electronic clinical quality measures (eCQMs): (1) Hospital Commitment to Health Equity measure, beginning with the CY 2023 reporting period/FY 2025 payment determination; (2) Screening for Social Drivers of Health measure, beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) Screen Positive Rate for Social Drivers of Health measure, beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (4) Cesarean Birth eCQM, beginning with the CY 2023 reporting period/FY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (5) Severe Obstetric Complications eCQM, beginning with the CY 2023 reporting period/FY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (6) Hospital-Harm—Opioid-Related Adverse Events eCQM, beginning with the CY 2024 reporting period/FY 2026 payment determination; (7) Global Malnutrition Composite Score eCQM, beginning with the CY 2024 reporting period/FY 2026 payment determination; (8) Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA), beginning with two voluntary reporting periods followed by mandatory reporting for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination; (9) Medicare Spending Per Beneficiary (MSPB) Hospital measure beginning with the FY 2024 payment determination; and (10) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total THA/TKA measure beginning with the FY 2024 payment determination.

We provide more details on each of these proposals in the subsequent sections.

a. Hospital Commitment to Health Equity Measure Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination and for Subsequent Years

(1) Background

Significant and persistent disparities in healthcare outcomes exist in the U.S. For example, belonging to a racial or ethnic minority group, living with a disability, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, being a member of a religious minority, living in a rural area, having a disability, or being near or below the poverty level, is often associated with worse health outcomes.[422] [423] [424] [425] [426] [427] [428] [429] [430] [431] Numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of hospital care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[432] [433] [434] [435] [436] [437]

Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*. We note that Meaningful Measures 2.0 is still under development.

[422] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA,* 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[423] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income Inequality and Thirty-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. *BMJ,* 346. Available at: *https://doi.org/10.1136/bmj.f521*.

[424] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and Equity of Care in U.S. Hospitals. *N Engl J Med,* 371(24), 2298–2308. Available at: doi: 10.1056/NEJMsa1405003.

[425] Polyakova, M, Udalova V, Kocks, G, Genadek K, Finlay K, Finkelstein AN. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. *Health Affairs,* 40(2), 307–316. Available at: *https://doi.org/10.1377/hlthaff.2020.02142*.

[426] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf*.

[427] HHS Office of Minority Health. (2020). Progress Report to Congress, 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Department of Health and Human Services. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf*.

[428] Heslin KC, Hall JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID–19–Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. *MMWR Morb Mortal Wkly Rep,* 70(5), 149. doi: 10.15585/mmwr.mm7005a1.

[429] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. medRxiv. doi: 10.1101/2020.07.21.20159327.

[430] Vu M, Azmat A, Radejko T, Padela AI. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. *Journal of Women's Health,* 25(6), 586–593. doi: 10.1089/jwh.2015.5517

[431] Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016). The Association Between Discrimination and the Health of Sikh Asian Indians. *Health Psychology,* 35(4), 351–355. *https://doi.org/10.1037/hea0000268*.

[432] CMS Office of Minority Health. (2020). Racial, Ethnic, and Gender Disparities in Healthcare in Medicare Advantage. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/files/document/2020-national-level-results-race-ethnicity-and-gender-pdf.pdf*.

[433] CMS Office of Minority Health. (Updated August 2018). Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf*.

[434] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. (2014). Racial Disparities in Knee and Hip Total Joint Arthroplasty: An 18-year analysis of national Medicare data. *Ann Rheum Dis.,* 73(12), 2107–15. Available at: doi:10.1136/annrheumdis-2013-203494.

[435] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. (2019). Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. *J Am Geriatr Soc.,* 67(8), 1672–1679. Available at: *https://doi.org/10.1111/jgs.15960*.

[436] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA,* 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[437] Tsai TC, Orav EJ, Joynt KE. (2014). Disparities in Surgical 30-day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *Ann Surg.,* 259(6), 1086–1090. Available at: doi: 10.1097/SLA.0000000000000326.

Readmission rates in the Hospital Readmission Reduction Program have shown to be higher among Black and Hispanic Medicare beneficiaries with common conditions, including congestive heart failure and acute myocardial infarction.[438] [439] [440] [441] [442] Data indicate that, even after accounting for factors such as socioeconomic conditions, members of racial and ethnic minority groups reported experiencing lower quality of healthcare.[443] Evidence of differences in quality of care received among racial and ethnic minority groups show worse health outcomes including diabetes complications such as retinopathy.[444] Additionally, inequities in the social determinants of health affecting these groups, such as poverty and healthcare access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks.[445]

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25592), we identified potential opportunities specific to the Hospital IQR Program by which we could leverage current measures or develop new measures to address the gap in healthcare disparities. In that rule, we sought public comment on addressing this gap, specifically requesting input on the inclusion of a structural measure to assess the degree of hospital leadership commitment to collecting and monitoring health equity performance data. We sought feedback on conceptual and measurement priorities to better illuminate organizational efforts to improve health equity, and on an appropriate measure regarding organizational commitment to health equity and accessibility for individuals with intellectual and developmental disabilities (86 FR 25593). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45414 through 45416), we summarized the public comments we received, including support for the development and implementation of a health equity structural measure. We refer readers to the ''Closing the Health Equity Gap in CMS Quality Programs—Request for Information'' (86 FR 45349) and ''Potential Future Efforts to Address Health Equity in the Hospital IQR Program'' (86 FR 45414) in the FY 2022 IPPS/LTCH PPS final rule for more details.

We note that the Agency for Healthcare Research and Quality (AHRQ) and The Joint Commission identified that hospital leadership plays an important role in promoting a culture of quality and safety.[446] [447] AHRQ research shows that hospital boards can influence quality and safety in a variety of ways; not only through strategic initiatives, but also through more direct interactions with frontline workers.[448] Because we are working toward the goal of all patients receiving high quality healthcare when hospitalized, regardless of individual characteristics, we are committed to supporting healthcare organizations in building a culture of equity that focuses on educating and empowering their workforce to recognize and eliminate health disparities. This includes patients receiving the right care, at the right time, in the right setting for their condition(s), regardless of those characteristics.

We believe that strong and committed leadership from hospital executives and board members is essential and can play a role in shifting organizational culture and advancing equity goals. Additionally, studies demonstrate that hospital leadership can positively influence culture for better quality, patient outcomes, and experience of care.[449] [450] [451] A systematic review of 122 published studies showed that strong leadership that prioritized safety, quality, and the setting of clear guidance with measurable goals for improvement resulted in a high-performing hospital with better patient outcomes.[452] We believe leadership commitment to health equity will have a parallel effect in contributing to a reduction in health disparities.

The Institute of Healthcare Improvement's (IHI's) research of 23 health systems throughout the U.S. and Canada also shows that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among disadvantaged populations.[453] This IHI study specifically identified concrete actions to make health equity a core strategy, including making health equity a leader-driven priority alongside organizational development structures and processes that support equity.[454] Based upon these findings, we believe that hospital leadership can be instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals to assess progress towards achieving equity priorities and ensuring high-quality care is equally accessible to all individuals. Therefore, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28492 through 28497), we proposed to adopt an attestation-based structural measure,

[438] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. (2011). Readmission Rates for Hispanic Medicare Beneficiaries with Heart Failure and Acute Myocardial Infarction. *Am Heart J.,* 162(2), 254–261 e253. Available at: *https://doi.org/10.1016/j.ahj.2011.05.009.*

[439] Centers for Medicare & Medicaid Services. (2014). Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures. Available at: *https://www.hhs.gov/guidance/document/medicare-hospital-quality-chartbook-performance-report-outcome-measures.*

[440] CMS Office of Minority Health. (Updated August 2018). Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[441] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. (2013). Chronic Obstructive Pulmonary Disease Readmissions at Minority-Serving Institutions. *Ann Am Thorac Soc.,* 10(6), 680–684. Available at: *https://doi.org/10.1513/AnnalsATS.201307-223OT.*

[442] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA,* 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[443] Nelson AR. (2003). Unequal Treatment: Report of the Institute of Medicine on Racial and Ethnic Disparities in Healthcare. *The Annals of Thoracic Surgery*, 76(4), S1377–S1381. doi: 10.1016/s0003–4975(03)01205–0.

[444] Peek, ME, Odoms-Young, A, Quinn, MT, Gorawara-Bhat, R, Wilson, SC, & Chin, MH. (2010). Race and Shared Decision-Making: Perspectives of African-Americans with diabetes. *Social Science & Medicine*, 71(1), 1–9. Available at: doi:10.1016/j.socscimed.2010.03.014.

[445] Department of Health and Human Services. (2021). Healthy People 2020: Disparities. Available at: *www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.*

[446] Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019. Available at: *https://psnet.ahrq.gov/primer/leadership-role-improving-safety.*

[447] Joint Commission on Accreditation of Healthcare Organizations, USA. Leadership Committed to Safety. Sentinel Event Alert. 2009 Aug 27;(43):1–3. PMID: 19757544.

[448] Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019: Available at: *https://psnet.ahrq.gov/primer/leadership-role-improving-safety.*

[449] Bradley EH, Brewster AL, McNatt Z, et al. (2018) How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. BMJ Qual Saf., 27(3), 218–225. doi:10.1136/bmjqs-2017-006574.

[450] Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. BMC Health Services Research, 17(1), 143. doi:10.1186/s12913-017-2078-6.

[451] Keroack MA, Youngberg BJ, Cerese JL, Krsek C, Prellwitz LW, Trevelyan EW. (2007). Organizational Factors Associated with High Performance in Quality and Safety in Academic Medical Centers. Acad Med., 82(12), 1178–86. doi: 10.1097/ACM.0b013e318159e1ff.

[452] Millar R, Mannion R, Freeman T, et al. (2013). Hospital Board Oversight of Quality and Patient Safety: A Narrative Review and Synthesis of Recent Empirical Research. *The Milbank Quarterly*, 91(4), 738–70. doi:10.1111/1468–0009.12032.

[453] Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. *NEJM Catalyst.* Available at: *https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556.*

[454] Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. *NEJM Catalyst.* Available at: *https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556.*

Hospital Commitment to Health Equity, beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years.

The first pillar of our strategic priorities [455] reflects our deep commitment to improvements in healthcare equity by addressing the health disparities that underly our health system. We developed this structural measure to assess hospital commitment to health equity across five domains (see Table IX.E–01. in the subsequent section) using a suite of organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. We believe these elements are actionable focus areas, and assessment of hospital leadership commitment to them is foundational. We also believe this measure will incentivize providers to collect and utilize data to identify critical equity gaps, implement plans to address said gaps, and ensure that resources are dedicated toward addressing healthcare equity initiatives. While many factors contribute to health equity, we believe this measure is an important step toward assessing hospital leadership commitment, and a fundamental step toward closing the gap in equitable care for all populations. We note that this measure is not intended to encourage hospitals to take action on any one given element of collected data, but instead encourages hospitals to analyze their own data to understand many factors, including race, ethnicity, and various social drivers of health, such as housing status and food security, in order to deliver more equitable care.

We believe this measure builds on current health disparities reporting, supports hospitals in quality improvement, promotes efficient and effective use of resources, and leverages available data. The five questions of the proposed structural measure are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement.[456]

This measure also aligns with our efforts under the Meaningful Measures Framework, which identifies high-priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes.[457] In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements.[458] We plan to address healthcare priorities and gaps with Meaningful Measures 2.0 by leveraging quality measures to promote equity and close gaps in care. The Hospital Commitment to Health Equity measure supports these efforts and is aligned with the Meaningful Measures Area of ''Equity of Care'' and the Meaningful Measures 2.0 goal to ''Leverage Quality Measures to Promote Equity and Close Gaps in Care.'' This measure also supports the Meaningful Measures 2.0 objective to ''Commit to a patient-centered approach in quality measure and value-based incentives programs to ensure that quality and safety measures address healthcare equity.''

(2) Overview of Measure

The Hospital Commitment to Health Equity measure assesses hospital commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. Table IX.E–01. includes the five attestation domains and the elements within each of those domains that a hospital must affirmatively attest to for the hospital to receive credit for that domain.

[455] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms*.

[456] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf*.

[457] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

[458] Centers for Medicare & Medicaid Services. (2021). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*. We note that Meaningful Measures 2.0 is still under development.

TABLE IX.E-01. THE HOSPITAL COMMITMENT TO HEALTH EQUITY MEASURES FIVE ATTESTATIONS

Attestation	**Elements: Select all that apply** (Note: Affirmative attestation of all elements within a domain will be required for the hospital to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Hospital commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your hospital has a strategic plan for advancing healthcare equity and that it includes all the following elements.	(A) Our hospital strategic plan identifies priority populations who currently experience health disparities. (B) Our hospital strategic plan identifies healthcare equity goals and discrete action steps to achieving these goals. (C) Our hospital strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our hospital strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a hospital is an important step in identifying and eliminating health disparities. Please attest that your hospital engages in the following activities.	(A) Our hospital collects demographic information, including self-reported race and ethnicity and/or social determinant of health information on the majority of our patients. (B) Our hospital has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our hospital inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using a certified EHR technology.
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your hospital engages in the following activities.	(A) Our hospital stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on hospital performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equally to all patients. Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our hospital participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your hospital engages in the following activities.	(A) Our hospital senior leadership, including chief executives and the entire hospital board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our hospital senior leadership, including chief executives and the entire hospital board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

The Hospital Commitment to Health Equity measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List), a list of measures under consideration for use in various Medicare programs.[459] The National Quality Forum (NQF) Measure Applications Partnership (MAP) Rural Health Advisory Group reviewed the MUC List and the Hospital Commitment to Health Equity measure (MUC 2021–106) in detail on December 8, 2021.[460] The MAP Rural Health Workgroup initially raised concerns that this measure may cause undue burden to rural hospitals that may not yet be directing resources or have available resources to dedicate toward implementing the measure. We acknowledge that for some hospitals, the implementation of this structural measure may impose additional data collection efforts. However, we believe this measure builds on hospitals'

[459] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464.*

[460] National Quality Forum. (2021). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting: Meeting Summary for December 8, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571.*

current quality improvement activities through participation in the Hospital IQR Program. Additionally, we believe the activities outlined in the previous table are foundational best practices for advancing health equity for patients and communities. The Rural Health Workgroup agreed that this is an important measure and for that reason should be added to the Hospital IQR Program measure set as the intent of the measure is to identify these gaps and make the needed investments in workforce training, leadership development, and other related areas to improve equity.[461] The MAP Rural Health Workgroup's recommendation was majority support for the Hospital Commitment to Health Equity measure.[462]

In addition, on December 9, 2021, the MAP Health Equity Advisory Group reviewed the 2021 MUC List.[463] The MAP Health Equity Advisory Group was convened at the request of CMS to provide input on the MUC List with the goal of reducing health disparities closely linked with social, economic, or environmental disadvantages.[464] The MAP Health Equity Advisory Group is charged with providing feedback related to the relative priority of each measure in advancing health equity, and input on potential data, reporting, and/or methodological concerns on reporting measures adjusting for healthcare disparities.[465] The MAP Health Equity Advisory Group provided input on potential unintended consequences or measurement gap areas related to health disparities.[466] After discussion of each measure under consideration, the Workgroup was polled on the potential impact on health disparities if the measure were to be included in a specific program. Like the MAP Rural Health Advisory Group, the MAP Health Equity Advisory Group agreed this is an important measure for advancing healthcare equity in the Hospital IQR Program and a fundamental first step toward future measure development and innovation.[467] The MAP Health Equity Advisory Group's feedback was supportive of this measure and its potential to decrease health disparities.[468]

The MUC List, including this measure (MUC2021–106), was also reviewed by the MAP Hospital Workgroup on December 15, 2021.[469] MAP stakeholders expressed concerns about whether measure data will be actionable and how improvements in clinical healthcare equity outcomes will be measured.[470] The MAP Hospital Workgroup had concerns about how this measure would be publicly reported, specifically, how it would be and interpreted by patients/consumers.[471] For these reasons, the MAP Hospital Workgroup recommended that the MAP not support the measure for rulemaking.[472] In response to this feedback, we wish to explain that we will publicly report the numerator indicating how many of the competencies hospitals attest to, and we refer readers to section IX.E.5.a.(3). for our proposed measure calculation methodology and section IX.E.5.a.(4). for the proposed public reporting. Thereafter, the MAP Coordinating Committee deliberated and ultimately voted to conditionally support this measure for rulemaking given its importance in being a first step towards the future development of outcome-based measures.[473] We agree that this measure is an important foundation of a comprehensive quality reporting program. Our approach to developing health equity measures is incremental and will evolve over time to capture healthcare equity outcomes in the Hospital IQR Program. We additionally believe this measure to be a building block that lays the groundwork for a future meaningful suite of measures that would assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics.

We have not submitted this measure for NQF endorsement at this time. We note that under section 1866(b)(3)(B)(viii)(IX)(aa) of the Act, each measure specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

(3) Measure Calculation

The Hospital Commitment to Health Equity measure consists of five domains, and a hospital will need to evaluate and determine whether it can affirmatively attest to each domain. Some of these domains have multiple elements to which a hospital must attest. For a hospital to affirmatively attest to a domain, and receive credit for

[461] National Quality Forum. (2021). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting: Meeting Summary for December 8, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571*.

[462] National Quality Forum. (2021). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting: Meeting Summary for December 8, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571*.

[463] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464*.

[464] National Quality Forum. (2022). Measure Applications Partnership Health Equity Advisory Group Virtual Review Meeting: Meeting Summary for December 9, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96599*.

[465] National Quality Forum. (2022). Measure Applications Partnership Health Equity Advisory Group Virtual Review Meeting: Meeting Summary for December 9, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96599*.

[466] National Quality Forum. (2022). Measure Applications Partnership Health Equity Advisory Group Virtual Review Meeting: Meeting Summary for December 9, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96599*.

[467] National Quality Forum. (2022). Measure Applications Partnership Health Equity Advisory Group Virtual Review Meeting: Meeting Summary for December 9, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96599*.

[468] National Quality Forum. (2022). Measure Applications Partnership Health Equity Advisory Group Virtual Review Meeting: Meeting Summary for December 9, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96599*.

[469] National Quality Forum. (2022). Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary for December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629*.

[470] National Quality Forum. (2022). Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary for December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629*.

[471] National Quality Forum. (2022). Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary for December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629*.

[472] National Quality Forum. (2022). Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary for December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629*.

[473] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698*.

that domain, the hospital will evaluate and determine whether it engages in each of the elements that comprise the domain. Each of the domains will be represented in the denominator as a point, for a total of 5 points (one per domain).

For example, for Domain 1 (''Hospital commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority''), a hospital will evaluate and determine whether its strategic plan meets each of the elements described in (A) through (D) (see Table IX.E–01.). If the hospital's plan meets all four of these elements, the hospital will affirmatively attest to Domain 1 and will receive a point for that attestation. A hospital will not be able to receive partial credit for a domain. In other words, if a hospital's strategic plan meets elements (A) and (B) but not (C) and (D), the hospital will not be able to affirmatively attest to Domain 1 and will not receive a point for that attestation.

The numerator will capture the total number of domain attestations that the hospital is able to affirm. For example, a hospital that affirmatively attests each element of the 5 domains will receive the maximum 5 points.

(4) Data Submission and Reporting

Specifications for the measure are available on the CMS Measure Methodology page with the file name ''Hospital Commitment to Health Equity Structural Measure Specifications'' at: *https://qualitynet.cms.gov/inpatient/iqr/resources*. Hospitals are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System. Hospitals will follow established submission and reporting requirements as previously finalized for structural measures and refer readers to section IX.E.10.i. of the preamble of this final rule for more details on our previously finalized data submission and deadline requirements for structural measures.

We proposed this measure for the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. In developing this proposal, we considered proposing an incremental approach to the implementation of this measure. However, we ultimately decided to propose mandatory reporting given the importance of this measure and how it aligns with our healthcare quality goal of closing the racial and ethnic disparity gaps.

We invited public comment on this proposal.

Comment: Many commenters supported the addition of the Hospital Commitment to Health Equity measure beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. Commenters supported this measure as a first step towards robust measurement of equitable healthcare delivery. Commenters believed this measure would help increase awareness for the importance of improving healthcare equity and send an important signal to hospital leadership. Additionally, commenters supported this measure, citing its importance for addressing disparities in healthcare outcomes and experience among populations that have been disadvantaged and/or underserved by the healthcare system. Others supported this measure because they believed it would assess commitment to establishing a culture of equity and help identify and address institutional biases. A commenter supported adoption of this measure because it highlights the importance of developing strategic initiatives, collecting data, and incorporating learnings in to care delivery and quality improvement initiatives. A commenter supported this measure because it presents the opportunity to address the lack of data that are comprehensive, consistent, and accurate to improve access and include participants from communities that have been disadvantaged and/or underserved by the healthcare system. A few commenters supported this measure as proposed.

Response: We thank commenters for their support of our proposal to adopt the Hospital Commitment to Health Equity measure and agree that adopting this measure is in line with our goal of improving healthcare equity.

Comment: A few commenters believed that starting with a structural measure is a good policy before proposing future process or outcome measures. A few commenters noted that the Hospital Commitment to Health Equity structural measure is strong for a structural measure. A few commenters agreed that this measure is actionable and will incentivize providers to collect and use data to close equity gaps. A commenter believed it would encourage hospitals to be more accountable for health disparities and help drive local commitment to health equity and advance health equity goals in the nation overall.

Response: We thank commenters for their support to adopt this measure into the Hospital IQR Program measure set.

Comment: A few commenters did not support this measure and recommended the measure should be further refined or alternative measure concepts should be developed. A commenter did not support and recommended hospitals be required to provide evidence in meeting each question. A few commenters did not support adopting the measure, citing concerns about whether the data will be meaningful and lead to progress or change.

Response: We appreciate commenters' recommendations to further refine or develop alternative measure concepts. We wish to note this measure has been reviewed by the Measure Application Partnership (MAP) Coordinating Committee, which voted to conditionally support the measure given its importance in being a first step towards the future development of outcome-based measures. We also acknowledge concerns related to whether this measure will lead to meaningful change. However, we respectfully disagree that data from this measure will not lead to progress or change. As previously stated, our approach to developing health equity measures is incremental and will evolve over time to capture healthcare equity outcomes in the Hospital IQR Program. We additionally believe this measure to be a building block that lays the groundwork for a more comprehensive suite of measures in the future that would assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics (87 FR 28496). We will monitor the data and any unintended consequences of the measure as part of standard measure maintenance.

Comment: A few commenters did not support this measure because of concerns that public reporting could be misleading to the public by failing to recognize other steps hospitals are taking to advance health equity. A few commenters expressed concern about public reporting and requested additional guidance on interpreting partial scores as to not mislead patients and communities. A commenter recommended alternative public reporting options including reporting the data as a part of a publicly available dataset instead of on the Care Compare website. A commenter requested clarification on how this measure will be publicly reported.

Response: We acknowledge commenters' concern about public reporting of this measure and interpretation by the public. We refer readers to sections IX.E.5.(a).(3). and IX.E.5.(a).(4). (Measure Calculation and Data Submission and Reporting, respectively) of this final rule for detailed descriptions of how we

calculate and publicly report this measure on the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*. This measure includes five attestation-based questions, each representing a separate domain of commitment. Hospitals receive one point for each domain to which they attest ''yes,'' stating they are meeting the required competencies. For each domain there are between one and four associated yes/no sub-questions for related structures or activities within the hospital. Hospitals will only receive a point for each domain if they attest ''yes'' to all related sub-questions. A hospital's score can be a total of zero to five points.[474] This measure will be publicly reported on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare*, or its successor website (87 FR 28562). We believe this measure will provide insightful information to healthcare providers and the public on the number of hospitals currently participating in health equity strategic planning, collecting data, using this data to identify equity gaps, establishing key performance indicators, and reviewing them with hospital senior leaders. We intend to provide educational materials as part of our outreach and public reporting of this measure to ensure understanding and interpretation of publicly reported data.

Comment: A few commenters did not support measure adoption due to resource constraints and timing of mandatory reporting and recommended delaying reporting to allow time for hospitals to build and deploy processes. A few commenters expressed concern that all hospitals will not have capabilities within their EHR to meet the criteria set forth by this measure. A few commenters expressed concern about the burden this may place on hospitals and systems, particularly those that are under resourced. Specifically, commenters noted attestation to this measure would be difficult for small rural hospitals.

Response: We acknowledge commenters' concerns regarding resources and timing of mandatory reporting; however, we believe achieving health equity is an issue, which deserves serious focus and rapid action for improvement. Although measure results will be publicly posted, we note that hospitals will receive credit for the reporting of their measure results regardless of their responses to the attestation questions because the Hospital IQR Program is a pay-for-reporting program.

With regard to comments about EHR capabilities, we are sensitive to the potential for increased administrative burden associated with adding new capabilities within EHR to meet the criteria set forth in this measure and will take commenters' feedback into consideration in future policy development. Furthermore, we acknowledge that facilitating quality improvement for rural hospitals and small hospitals can present unique challenges and is a high priority under the Meaningful Measures Framework. We continue to consider ways to support small and rural hospital efforts toward achieving health equity.

Comment: A few commenters expressed concern about this measure not being NQF endorsed.

Response: We thank commenters for their recommendations. While we recognize the value of measures undergoing NQF endorsement review, given the urgency of achieving health equity and, as there are currently no NQF-endorsed measures that address hospital commitment to health equity, we believe it is important to implement this measure as soon as possible. We note that under section 1866(b)(3)(B)(viii)(IX)(aa) of the Act, each measure specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

Comment: A commenter requested clarification on whether this measure would be a pay-for-reporting measure since it is part of the Hospital IQR Program, or if affirmation in each of the five attestation domains would have a performance value.

Response: We note that the Hospital IQR Program is a pay-for-reporting program, and hospitals' payments are not based on their performance on measures. We note that hospitals will receive credit for the reporting of their measure results regardless of their responses to the attestation questions.

Comment: A commenter requested clarification on how this measure will be validated.

Response: We thank the commenter for their question. We wish to clarify that this measure will not be included in the Hospital IQR Program validation at this time. We require all hospitals participating in the Hospital IQR Program to complete the Data Accuracy and Completeness Agreement (DACA) each year which requires attestation that all of the information reported to CMS is accurate and complete (77 FR 53554).

Comment: A few commenters indicated that hospitals are not yet uniformly collecting disaggregated sociodemographic data and suggested that as a first step, we encourage hospitals to collect disaggregated data since it leads to a more complete data set. A commenter recommended changing the language to require hospitals to stratify performance indicators by demographic variables and state which demographic variables hospitals must use when stratifying quality data.

Response: We appreciate commenters' recommendations to uniformly collect disaggregated data and interest regarding the collection and standardization of sociodemographic data. We believe this measure allows for significant flexibility in the approach to data collection and believe this is an appropriate first step for this structural measure and our first health equity-related quality measure. Though we will not be revising the measure to require stratification of performance indicators by identified demographic variables at this time, we will take commenters' feedback into consideration for future policy development. Additionally, we refer readers to our Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—Request for Information in section IX.B. for more information about potential future measure stratification.

Comment: A commenter suggested that for purposes of the Hospital IQR Program, we focus on assessing clinical quality rather than the quality of data collection.

Response: We appreciate the commenters' feedback. We intend to continue research and assessments on improving clinical quality through quality measurement reporting to achieve health equity and have evaluated research, existing frameworks, and various tools in the development of

[474] Centers for Medicare & Medicaid Services. (2022). Hospital Commitment to Health Equity Structural Measure Specifications. Available at: *https://qualitynet.cms.gov/files/62629ee35e40610016f30140?filename=Hosp_Commit_HlthEqStrct_Meas.pdf*.

this measure as described in section IX.E.5.a. As discussed in the proposed rule, the five domains of this measure were adapted from the CMS Office of Minority Health's Building and Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement (87 FR 28492). Further, we believe this measure is an important first step toward development of a more comprehensive suite of measures in the future (87 FR 28496). Additionally, the MAP Rural Health Workgroup agreed that this is an important measure and that the intent of the measure is to identify gaps and make the needed investments in workforce training, leadership development, and other related areas to improve equity (87 FR 28496).

Comment: A commenter recommended that if we move forward with the Z codes and social drivers of health screening quality measures, there is no need to attest to data collection and analysis.

Response: We thank the commenter for their recommendation regarding minimizing provider reporting burden by removing data collection and analysis (Domain 2 and Domain 3) attestation questions if we move forward with finalization of other proposals such as Z codes (discussed as a RFI in section II.D.13.d. of this final rule) and social drivers of health screening quality measures such as the Screening for Social Drivers of Health and Screen Positive Rate both discussed in section IX.E.5.b. of this final rule. We agree that any future measures or measure refinements should carefully consider alignment with other quality measure reporting requirements and efforts in a manner that minimizes provider reporting burden. We will take commenters' feedback into consideration in future policy development.

Comment: A few commenters raised concerns that the measure is potentially duplicative of other measure reporting requirements such as eCQMs. A commenter questioned the need for this measure given that there are equity standards that are already developed. A commenter recommended a complete environment scan, listening sessions, focus groups, and/or a technical expert panel to catalogue what hospitals are doing to identify and address health disparities and ensure there is no redundancy in reporting requirements. Another commenter stated that a requirement of the Hospital Readmissions Reduction Program is to provide hospitals with risk-stratified reports, thus, requiring stratified reports in Domain 3 in this structural measure is duplicative. A few commenters recommended considering opportunities for alignment with existing tools to reduce reporting burden.

Response: We thank the commenter for their recommendations, and we will continue to engage interested parties as we continue to build on our efforts to address unmet needs. Additionally, we wish to refer readers to our thorough discussion and RFIs on our ongoing evaluation of appropriate initiatives to reduce health disparities (see section IX.B., ''Closing the Health Equity Gap in CMS Hospital Quality Programs—Request for Information,'' in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45349)) as well as section IX.B. of this final rule). We additionally appreciate commenter concerns related to potentially duplicative efforts and continually look for ways to minimize provider reporting burden. We will take this into consideration for future program years. We wish to reiterate that our approach to developing health equity measures is incremental and will evolve over time to capture healthcare equity outcomes in the Hospital IQR Program. We additionally believe this measure to be a building block that lays the groundwork for a more comprehensive suite of measures that would assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics.

Additionally, we continually look for ways to minimize provider reporting burden and do not believe that this measure is duplicative of other efforts or currently available eCQMs in the Hospital IQR Program at this time. With regard to the commenters recommending alignment, we interpret the commenters to mean that they have existing tools integrated into their EHRs or similar systems that assess the domains evaluated by this measure. We agree and encourage hospitals to utilize existing tools in their assessment of meeting reporting requirements of this measure.

In regard to the comment on the Hospital Readmissions Reduction Program, while the Hospital Readmissions Reduction Program does provide hospitals with reports stratified by dual-eligibility, these reports are specific to the six condition/procedure specific readmissions measures within that program. Therefore, we believe that the data collected regarding Hospital Commitment to Health Equity will be complementary to the stratified data provided to hospitals within the Hospital Readmissions Reduction Program.

Comment: Several commenters recommended that we broaden the scope of this measure to address more health equity factors and indicators. A few commenters believed that we should require collection of more granular and more specific data in order to thoroughly assess a hospital's commitment to equity. A commenter recommended inclusion of the elderly and veterans. Another commenter expressed concern this measure will not provide specific enough information to identify equity gaps and determine where improvements are most needed.

Response: We appreciate commenters recommendations. At this time, this measure is a hospital-level measure that is assessing hospital commitment to health equity. We believe that the domains covered by this measure are inclusive of a hospital's commitment to the care of the population they serve, inclusive of the elderly and veterans. We refer readers to section IX.E.5.b. for discussion of the Social Drivers of Health measures and section IX.E.5.f. for discussion of the Global Malnutrition Composite Score eCQM which we believe address further the health equity factors. With regard to commenter concerns about sufficient measure specificity to identify equity gaps, as stated in the proposed rule, we encourage providers to analyze their own data to understand many factors, including race, ethnicity, and various drivers of health, such as housing stability and food security, in order to deliver more equitable care (87 FR 28493). The five domains of this measure were adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement, and we encourage its use for data analysis to further understand the factors we have highlighted.[475] Additionally, we wish to highlight the recently published CMS Framework for Health Equity 2022–2032 that provides guidance on designing, implementing, and operationalizing policies and programs.[476]

[475] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.*

[476] Centers for Medicare & Medicaid Services. (2022). CMS Framework for Health Equity 2022–2032. Available at: *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

Comment: A commenter recommended we remove the requirement to collect data relating to race and ethnicity out of concern that collecting the data might worsen patient care and trust. Another commenter recommended removal of references to drivers of health data to maintain focus on healthcare related actions.

Response: We appreciate commenters' concern and recognize the importance of establishing and maintaining patient trust in health equity initiatives. We wish to clarify that this measure does not require the collection of race and ethnicity data as a part of reporting. Rather, the measure assesses hospital commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. We believe this measure is an important foundational measure for improving health equity among those that have been disadvantaged and/or underserved by the healthcare system, and there is substantial research showing differences in care and experiences among these populations (87 FR 28492 through 28493). We encourage providers to analyze their own data to understand the many factors, including race, ethnicity, and various drivers of health, such as housing stability and food security, in order to deliver more equitable care. Further, we note that although measure results will be publicly posted, hospitals will receive credit for the reporting of their measure results regardless of their responses to the attestation questions.

Comment: A few commenters expressed concern about the need for training and education on implementing and structuring a program to engage leadership in improving health equity.

Response: We appreciate commenters' concerns and agree that training and education is important for establishing and implementing any new measures in the Hospital IQR Program. We wish to highlight the various resources available through the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, from which this measure was adapted, and the recently published CMS Framework for Health Equity 2022–2032 that provides guidance on designing, implementing, and operationalizing policies and programs.[477] [478]

Comment: A commenter expressed concern about including Domain 3: Data Analysis in this attestation-based measure and recommended removing attestation to a performance dashboard that stratifies findings from this proposal as this activity is viewed as a next step. Another commenter expressed concerns that Domain 4 would be resource intensive as described. Instead, the commenter recommended this should be optional with a requirement to attest whether equity is embedded in the hospital's quality improvement processes and workflows or attest to having initiatives focused on addressing an inequity identified in hospital data analysis. A commenter recommended revising specifications for Domains 2, 3, and 4 as attestations to the inclusion of hospitals' strategic plans, timelines for implementation, and specific steps for achieving all five domains. A commenter recommended adding attestations regarding community and patient perspectives related to health equity and ongoing education to the leadership domain.

Response: We appreciate the commenter's recommendations regarding domains. As we noted in the FY 2023 IPPS/LTCH PPS proposed rule, we believe all the activities outlined in the five domains of this attestation measure are foundational best practices for advancing health equity for patients and communities (87 FR 28496). We acknowledge not all hospitals will be engaged in all activities outlined across the five domains. Further, we wish to reiterate that hospitals will receive credit for the reporting of their measure results regardless of their responses to the attestation questions. As previously stated, our approach to developing health equity measures is incremental and will evolve over time to capture healthcare equity outcomes in the Hospital IQR Program. We additionally believe that a hospital's attestation to the *action* of the elements of the domains and not just the inclusion of the elements is important. Moreover, we do not anticipate that every hospital will be able to affirmatively attest to each domain. We note that this measure will be included in the Hospital IQR Program beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. With each additional year, we hope to see that each hospital is able to attest to more domains as part of their growth strategy and commitment to equity-focused organizational improvements. We expect variability across hospitals and we believe this is important as part of our long-term strategy to improve health equity.

Comment: Many commenters expressed concern about the scoring of this structural measure, citing it as an ''all or nothing'' approach, and recommended awarding partial credit within each domain. Specifically, many requested to receive a point for each element within a domain, resulting in a denominator of 11 rather than 5. A commenter recommended scoring collection of social drivers of health information separately from demographic data, suggesting this would highlight the importance of capturing both sets of data.

Response: We thank the commenters for their feedback. We believe the five domains of this measure are actionable focus areas, and assessment of hospital leadership commitment to them is foundational. We also believe this measure will incentivize providers to collect and utilize data to identify critical equity gaps, implement plans to address said gaps, and ensure that resources are dedicated toward addressing healthcare equity initiatives (87 FR 28493). The five questions of the proposed structural measure are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement (87 FR 28494). We believe that each element within a domain is important together to help hospitals identify, prioritize, and take action on health disparities. Additionally, we wish to note that the Hospital IQR Program is a pay-for-reporting program, and hospitals are not scored based on their performance on measures.

Comment: A commenter requested clarification on whether providers would receive a special designation for attesting to all five domains.

Response: We appreciate the commenter's request for clarification. We wish to clarify that we are not proposing a hospital designation related to health equity at this time. We commend and encourage hospitals to establish the necessary suite of equity-

[477] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.*

[478] Centers for Medicare & Medicaid Services. (2022). CMS Framework for Health Equity 2022–2032. Available at: *https://www.cms.gov/files/document/cms-framework-health-equity.pdf.*

focused organizational competencies aimed at achieving health equity.

Comment: Many commenters recommended CMS provide guidance to ensure attestations are meaningful, accurate, complete, and applied consistently across hospitals. Specifically, commenters requested we provide a standard set of definitions and key terms. Several commenters recommended establishing guidelines or minimum benchmarks for each domain to create a more standardized methodology to reduce ambiguity. Commenters expressed concerns that the lack of clear definitions and benchmarks limit data from being truly actionable with respect to illuminating equity gaps, as the elements allow a large degree of ambiguity on how hospitals are evaluating whether they have met the requirements. A commenter requested clarification for which instances a hospital's participation in a regional framework (such as an HIE and related use cases), would constitute evidence of data collection, data analysis, and quality improvement. A commenter requested clarification on the intent by leaving the questions subject to interpretation.

Response: We thank commenters for their feedback. Regarding a more standardized measure methodology, we note that the measure specifications as proposed (87 FR 28497) are available on the CMS Measure Methodology page with the file name ''Hospital Commitment to Health Equity Structural Measure Specifications'' at: *https://qualitynet.cms.gov/inpatient/iqr/resources*. As stated in the proposed rule, the five domains of this measure were adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement, and we encourage its use for data analysis to further understand the factors we have highlighted (87 FR 28492). Further, we stated that this measure is an important foundation and the MAP Coordinating Committee supported the measure for rulemaking given its importance in being a first step towards the future development of outcome-based measures (87 FR 28496). Additionally, we wish to highlight the recently published CMS Framework for Health Equity 2022–2032 that provides guidance on designing, implementing, and operationalizing policies and programs.[479] We encourage providers to analyze their own data to understand many factors, including race, ethnicity, and various drivers of health, such as housing stability and food security, and encourage hospitals to use these data to set specific, measurable, attainable, and realistic, and time-based (SMART) goals that support delivery of equitable care (87 FR 28493).

We wish to clarify that we will provide educational and training materials to help with consistent implementation which will be conveyed through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet website.

Regarding the request for benchmarks and clarification on which instances a hospital's participation in a regional framework would constitute evidence of data collection, data analysis, and quality improvement, we remind readers that the Hospital IQR Program is a pay-for-reporting program, and therefore, there are no set performance targets. We refer readers to the measure specifications at *https://qualitynet.cms.gov/inpatient/iqr/resources* for more details.

Comment: Many commenters recommended starting with voluntary reporting beginning with the CY 2023 reporting period. A commenter recommended voluntary reporting to allow for time to refine measure elements and direct educational and technical assistance resources appropriately. A commenter recommended delaying mandatory reporting until at least CY 2024 to allow to allow additional time to allocate the necessary resources to fully implement the measure elements. Several commenters recommended delaying mandatory reporting until additional testing and greater specificity is further developed.

Response: We appreciate commenters' concerns about mandatory reporting; however, we believe that achieving health equity is a pressing issue which deserves serious focus and rapid action. We note that hospitals will receive credit for the reporting of their measure results regardless of their responses to the attestation questions. We emphasize that the measure was proposed for inclusion beginning in the CY 2023 reporting period/FY 2025 payment determination, which will allow hospitals time during the remainder of CY 2022 to begin assessing their activities and levels of engagement in the identified domains. We additionally believe this measure to be a building block that lays the groundwork for a more comprehensive suite of measures that would assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics.

Comment: A commenter requested allowing hospitals to report as a system to reduce burden and duplicative reporting.

Response: We thank the commenter for their request. We interpret the commenter to mean that they want a hospital system to report as one instead of separately by hospital. We wish to clarify that as part of the measure reporting, a hospital would be required to report under their CMS certification number (CCN) as part of their normal Hospital IQR Program reporting operations.

Comment: A commenter recommended focusing on hospital-level practices and data, promoting collaboration between hospitals, ensuring measures are appropriately specified and tested before implementation, establishing feedback loops, fostering alignment and standardized approaches to data collection, and prioritizing the use of existing data. A commenter recommended enhanced coordination with local public health systems and sharing the measure data in the Community Health Needs Assessment (CHNA) processes, which are shared with local public health systems to guide public and private resource allocation.

Response: We appreciate the commenter's recommendations. We agree that these are all important elements to monitoring and evaluating a quality reporting program. We believe this measure, the other measures we are proposing for adoption in the Hospital IQR Program, and our current measure set address a range of priorities. We are consistently committed to developing, adopting, assessing, and maintaining appropriate measures to put patients first and ensure they are empowered to make decisions about their own healthcare along with their clinicians by using information from data-driven insights. We equally encourage hospitals to collaborate, both with other hospitals and with local, state, and regional partners to align where possible to help supplement our efforts. We will continue to take these recommendations into consideration for future policy development.

Comment: Another commenter recommended robust evaluation and monitoring of the measure.

[479] Centers for Medicare & Medicaid Services. (2022). CMS Framework for Health Equity 2022–2032. Available at: *https://www.cms.gov/files/document/cms-framework-health-equity.pdf*.

Response: We thank the commenter for their feedback. We will monitor measure implementation and data reporting as part of standard program and measure review. After consideration of the public comments we received, we are finalizing the proposal as proposed.

b. Adoption of Two Social Drivers of Health Measures Beginning With Voluntary Reporting in the CY 2023 Reporting Period and Mandatory Reporting Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

Health-related social needs (HRSNs), which we have previously defined as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization.[480] We believe that consistently pursuing identification of HRSNs will have two significant benefits. First, because social risk factors disproportionately impact historically [481] Second, these measures could support ongoing hospital quality improvement initiatives by providing data with which to stratify patient risk and organizational performance.

Further, we believe collecting patient-level HRSN data through screening is essential in the long-term in encouraging meaningful collaboration between healthcare providers and community-based organizations and in implementing and evaluating related innovations in health and social care delivery. We note that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars [482] and a Biden-Harris Administration priority.

As a first step towards addressing the role of HRSNs in closing the health equity gap, we have developed two evidence-based measures—Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health. These two Social Drivers of Health measures will support identification of specific risk factors for inadequate healthcare access and adverse health outcomes among patients. We note that these measures will enable systematic collection of HRSN data which aligns with our other efforts, including the CY 2023 Medicare Advantage and Part D proposed rule in which we proposed that all Special Needs Plans (SNPs) complete health risk assessments (HRAs) of enrollees that include specific standardized questions on housing stability, food security, and access to transportation (87 FR 1858). (We also note that this proposal was finalized with modification in the CY 2023 Medicare Advantage and Part D final rule (87 FR 27726). We finalized that all SNPs include one or more questions on housing stability, food security, and access to transportation in their HRA using questions from a list of screening instruments specified in sub-regulatory guidance instead of the proposed use of the same standardized questions (82 FR 27726)).

These standardized measures will identify patients with HRSNs, who are known to experience the greatest risk of poor health outcomes, thereby improving the accuracy of high-risk prediction calculations. Improvement in risk prediction has the potential to reduce healthcare access barriers, address the disproportionate expenditures attributed to high-risk population groups, and improve the hospital's quality of care.[483] [484] [485] [486] Further, these data could guide future public and private resource allocation to promote targeted collaboration between hospitals and health systems and appropriate community-based organizations and ultimately contribute to improved patient outcomes following inpatient hospitalization.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28497 through 28506), we proposed voluntary reporting of these two measures beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We believe incremental implementation of these measures beginning with one year of voluntary reporting will allow hospitals who are not yet screening patients for HRSNs to get experience with the measure and equally allow hospitals who already undertake screening efforts to report data already being collected.

We provide further details on both measures in the subsequent discussion. Additionally, consistent with our strategy to incorporate social drivers of health factors into Medicare quality reporting and payment, we refer readers to section II.D.13.(d). where we sought comment on how the reporting of diagnosis codes may improve our ability to advance health equity.

[480] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.* Accessed: November 23, 2021.

[481] American Hospital Association. (2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed: January 18, 2022. Available at: *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.*

[482] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[483] Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: *https://doi.org/10.1377/hlthaff.2020.01742.*

[484] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752.*

[485] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/.*

[486] Jaffrey, J.B., Safran, G.B., Addressing Social Risk Factors in Value-Based Payment: Adjusting Payment Not Performance to Optimize Outcomes and Fairness. Health Affairs Blog, April 19, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/forefront.20210414.379479/full/.*

(1) Screening for Social Drivers of Health Measure

(a) Background

In the FY 2022 IPPS/LTCH PPS final rule, we sought feedback on the development of new measures that could address the gap in existing health disparities, focusing on social risk factors for which providers should screen (85 FR 45414). As a result, we identified the Screening for Social Drivers of Health measure, which assesses the percent of patients admitted to the hospital who are 18 years or older at time of admission and are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Health disparities manifest primarily as worse health outcomes in population groups where access to care is inequitable.[487] [488] [489] [490] [491] Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time.[492] [493] [494] Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health outcomes.[495] [496] [497] While widespread interest in addressing HRSNs exists, action is inconsistent, with 92 percent of hospitals screening for one or more of the five HRSNs—food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety—specified in the proposed measures, but only 24 percent of hospitals screening for all five HRSNs.[498]

Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality-based payment programs.[499] [500] In 2017, CMS' Center for Medicare and Medicaid Innovation (CMMI) launched the Accountable Health Communities (AHC) Model to test the impact of systematically identifying and addressing the HRSNs of Medicare and Medicaid beneficiaries (through screening, referral, and community navigation on their health outcomes and related healthcare utilization and costs).[501] [502] [503] [504] Although there are models that address HRSNs, the AHC Model is one of the first federal pilots to systematically test whether identifying and addressing core HRSNs improves healthcare costs, utilization, and outcomes.[505] It also tested the ability of hospitals and health systems to implement HRSN screening, referral, and community navigation in over 600 clinical sites in 21 states.[506] The AHC Model has a 5-year period of performance that began in May 2017 and will end in April 2022, with beneficiary screening beginning in the summer of 2018 following an implementation period.[507] [508]

While social risk factors account for 50 to 70 percent of health outcomes, the mechanisms by which this connection emerges are complex and multifaceted.[509] [510] [511] [512] The persistent

[487] Seligman, H.K., & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: *https://pubmed.ncbi.nlm.nih.gov/30444684/*.

[488] The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf*.

[489] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress*.

[490] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[491] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[492] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress*.

[493] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[494] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity. Available at: *https://www.aafp.org/dam/AAFP/documents/patient_care/everyone_project/team-based-approach.pdf*.

[495] Institute of Medicine. (2014). Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/18951*.

[496] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. (2016). Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532*.

[497] Centers for Disease Control and Prevention. CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html*. Accessed November 17, 2021.

[498] TK Fraze, AL Brewster, VA Lewis, LB Beidler, GF Murray, CH Colla. Prevalence of screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence by US physician practices and hospitals. JAMA Network Open 2019; 2:e1911514.10.1001/jamanetworkopen.2019.11514.31532515.

[499] Zhang Y, Li J, Yu J, Braun RT, Casalino LP (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open*. 2021;4(6):e2113212. doi:10.1001/jamanetworkopen.2021.13212.

[500] Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. JAMA, 324(10), 975–983. *https://doi.org/10.1001/jama.2020.13129*.

[501] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion*.

[502] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532*.

[503] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[504] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: *https://innovation.cms.gov/innovation-models/ahcm*.

[505] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[506] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[507] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[508] We note that the model officially concluded in April 2022 but many awardees are continuing with no-cost extensions to continue utilizing unspent cooperative agreement funding and all awardees will conclude by April 2023.

[509] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*. Accessed November 23, 2021.

[510] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. (2020). Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity.

[511] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752*.

[512] The Physicians Foundation. (2021). Viewpoints: Social Determinants of Health. Available at: *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf*. Accessed December 8, 2021.

interactions between individuals' HRSNs, medical providers' practices/behaviors, and community resources significantly impact healthcare access, quality, and ultimately costs, as described in the CMS Equity Plan for Improving Quality in Medicare.[513] [514] In their 2018 survey of 8,500 physicians, The Physicians Foundation found almost 90 percent of physician respondents reported their patients had a serious health problem linked to poverty or other social conditions.[515] Additionally, associations between disproportionate health risk, hospitalization, and adverse health outcomes have been highlighted and magnified by the COVID–19 pandemic.[516] [517]

In developing this measure, we identified core HRSN domains based on the following criteria: (1) The availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations, and associated costs; (2) the HRSNs can be screened and identified in the inpatient setting prior to hospital discharge, addressed by community-based services, and potentially improve healthcare outcomes, including reduced hospital re-admission; and (3) the HRSNs are not systematically addressed by healthcare providers.[518] Based on those criteria, the following five domains were selected to screen for social risk factors in Medicare and Medicaid beneficiaries under the AHC Model: (1) Food insecurity; (2) housing instability; (3) transportation needs; (4) utility difficulties; and (5) interpersonal safety. In addition to established evidence of their association with health status, risk, and outcomes, these five domains were selected because they can be assessed across the broadest spectrum of individuals in a variety of settings.[519] [520] [521] The five core HRSN domains are described in Table IX.E–02.

[513] Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Accessed January 18, 2022. Available at: *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf*.

[514] Centers for Medicare & Medicaid Services Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid%20Services%20%28CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%20stakeholder%20input*.

[515] The Physicians Foundation. (2019). Viewpoints: Social Determinants of Health. Available at: *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf*. Accessed December 8, 2021.

[516] Centers for Disease Control and Prevention. (2020). CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html*. Accessed November 17, 2021.

[517] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*. Accessed November 23, 2021.

[518] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[519] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[520] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: *https://innovation.cms.gov/innovation-models/ahcm*.

[521] Kamyck, D., Senior Director of Marketing. (2019). CMS releases standardized screening tool for health-related social needs. Activate Care. Available at: *https://blog.activatecare.com/standardized-screening-for-health-related-social-needs-in-clinical-settings-the-accountable-health-communities-screening-tool/*.

TABLE IX.E-02. THE FIVE CORE HRSN DOMAINS TO SCREEN FOR SOCIAL DRIVERS OF HEALTH

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain access to adequate quality and quantity of food at the household level. It is associated with diminished mental and physical health and increased risk for chronic conditions.[522,523] Individuals experiencing food insecurity often have inadequate access to healthier food options which can impede self-management of chronic diseases like diabetes and heart disease, and require individuals to make personal trade-offs between food purchases and medical needs, including prescription medication refills and preventive health services.[524,525] Food insecurity is associated with high-cost healthcare utilization including emergency department (ED) visits and hospitalizations.[526,527,528]
Housing Instability	Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence.[529,530] Population surveys consistently show that people from some racial and ethnic minority groups constitute the largest proportion of the U.S. population experiencing unstable housing.[531] Housing instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services.[532,533]
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living.[534] Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with impaired mobility, residents of rural areas, and people from some racial and ethnic minority groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and

[522] Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124.

[523] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[524] Seligman, H.K., & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: *https://pubmed.ncbi.nlm.nih.gov/30444684/*.

[525] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285*.

[526] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

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[529] Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414*.

[530] Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[531] Henry, M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: *https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf*.

[532] Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414*.

[533] Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379–387. Available at: *https://jech.bmj.com/content/jech/73/5/379.full.pdf*.

[534] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285*.

[535] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285*.

[536] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[537] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[538] Shier, G., Ginsburg, M., Howell, J., Volland, P., & Golden, R. (2013). Strong Social Support Services, Such as Transportation And Help For Caregivers, Can Lead To Lower Health Care Use And Costs. Health Affairs, 32(3), 544–551. Available at: *https://doi.org/10.1377/hlthaff.2012.0170*.

[539] Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379–387. Available at: *https://jech.bmj.com/content/jech/73/5/379.full.pdf*.

[540] Wright, B.J., Vartanian, K.B., Li, H.F., Royal, N., & Matson, J.K. (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. Health Affairs, 35(1), 20–27. Available at: *https://doi.org/10.1377/hlthaff.2015.0393*.

[541] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[542] Henry M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: *https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf*.

[543] Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414*.

Domain	Description
	more frequent utilization of high-cost healthcare services including emergency medical services, EDs, and hospitalizations.[535,536,537,538]
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity.[539] Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements.[540]
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes screening for exposure to intimate partner violence, child abuse, and elder abuse.[541] Exposure to violence and social isolation are reflective of individual-level social relations and living conditions that are directly associated with injury, psychological distress, and death in all age groups.[542,543]

Utilization of screening tools to identify the burden of unmet HRSNs can be a helpful first step in identifying necessary community partners and connecting individuals to resources in their communities. We believe collecting data across the same five HRSN domains that were screened under the AHC Model will illuminate their impact on health outcomes and disparities and the care-cost burden for hospitals, and in particular for hospitals that serve patients with disproportionately high levels of social risk factors. This data collection could inform meaningful and sustainable solutions for other provider-types through similar collections in other quality reporting programs.[544 545 546 547 548]

[544] The Physicians Foundation: 2020 Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf*.

[545] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress*.

[546] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[547] Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: *https://doi.org/10.1377/hlthaff.2020.01742*.

[548] De Marchis, E., Knox, M., Hessler, D., Willard-Grace, R., Oliyawola, JN, et al. (2019). Physician Burnout and Higher Clinic Capacity to Address Patients' Social Needs. The Journal of the American Board of Family Medicine, 32 (1), 69–78.

For data collection of this measure, providers could use a self-selected screening tool and collect these data in multiple ways, which can vary to accommodate the population they serve and their individual needs.[549] [550] One example of such data collection is the AHC Model, which uses the standard 10-item AHC Health-Related Social Needs Screening Tool to enable providers to identify HRSNs in the five core domains (described in Table IX.E–02.) of community-dwelling Medicare, Medicaid, and dually eligible beneficiaries.[551] Since its inception, the AHC Model has been implemented across many care delivery sites in diverse geographic locations across the U.S.[552] More than one million Medicare and Medicaid beneficiaries have been screened using the AHC Health-Related Social Needs Screening Tool, which has been evaluated psychometrically and demonstrated evidence of both reliability and validity, including inter-rater reliability and concurrent and predictive validity.[553] Moreover, the screening instrument can be implemented in a variety of clinical settings, including primary care, EDs, labor and delivery units, inpatient units (including mental and behavioral health settings), and other places where patients seek healthcare.[554]

The intent of this measure is to promote adoption of HRSN screening by hospitals. We encourage hospitals to use the screening as a basis for developing their own individual action plans (which could include navigation services), as well as opportunities for initiating and improving partnerships between healthcare delivery and community-based services. This effort will yield actionable information to close the disparity gap by encouraging hospitals to identify patients with HRSNs, with a reciprocal goal of partnering with community-based organizations to connect those individuals to community support to help address those risks.

Under our Meaningful Measures Framework,[555] the Screening for Social Drivers of Health measure addresses the quality priority of ''Work with Communities to Promote Best Practices of Healthy Living'' through the Meaningful Measures Area of ''Equity of Care.'' Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''healthcare equity'' priority area and aligns with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to ''develop and implement measures that reflect social and economic determinants.'' [556] Development and proposal of this measure also aligns with our strategic pillar to advance health equity by addressing the health disparities that underlie our health system.[557]

This measure (alongside the Screen Positive Rate for Social Drivers of Health measure) will be the first patient-level measurement of social drivers of health in the Hospital IQR Program. We believe this measure is appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings. Screening during inpatient hospitalization will allow healthcare providers to identify and potentially help address HRSNs as part of discharge planning and contribute to long-term improvements in patient outcomes. This will have a direct and positive impact on hospital quality performance. Collecting baseline data via this measure is crucial in informing design of future measures that could enable us to set appropriate performance targets for hospitals.

(b) Overview of Measure

The Screening for Social Drivers of Health measure assesses whether a hospital implements screening for all patients that are 18 years or older at time of admission for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. To report on this measure, hospitals will provide: (1) The number of inpatients admitted to the hospital who are 18 years or older at time of admission and who are screened for all [558] of the five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety; and (2) the total number of patients who are admitted to the hospital who are 18 years or older on the date they are admitted.

The Screening for Social Drivers of Health (MUC21–136) measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List).[559] The MAP Rural Health Workgroup and the Health Equity Advisory Group reviewed the measure on December 8, 2021, and December 9, 2021, respectively. Both groups indicated that screening for social risk factors would inform future efforts to expand capabilities to capture data that demonstrate the extent to which improvements in healthcare quality contribute to reductions in health disparities and the impact of serving patients at higher risk for adverse health outcomes on healthcare quality at the organization level. Although MAP stakeholders expressed concerns regarding standardization and the need to emphasize the link between the measure and better healthcare outcomes for patients, the measure developer stated that the focus at this point was to establish standard social drivers of health screening measures and not to dictate to hospitals and providers which tool they use or how to address the needs of their patients, citing that multiple CMS models have demonstrated the feasibility of implementing HRSN screening. However, we acknowledge the value and importance of tools which support

[549] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: *https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison.* Accessed January 18, 2021.

[550] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights (June 2021). Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.* Accessed January 18, 2021.

[551] More information on the HRSN Screening Tool is available at: *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[552] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[553] Lewis C., Wellman R., Jones S., Walsh-Bailey C., Thompson E., Derus A., Paolino A., Steiner J., De Marchis E., Gottlieb L., and Sharp A. (2020). Comparing the Performance of Two Social Risk Screening Tools in a Vulnerable Subpopulation. J Family Med Prim Care. 2020 Sep; 9(9): 5026–5034. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/.*

[554] CMS. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.*

[555] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[556] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[557] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[558] In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28502), we stated ''for each of the five HRSNs.'' We have updated the preamble of the final rule to state ''for all five HRSNs'' as per the measure specifications and in alignment with the language throughout the preamble.

[559] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464.*

the interoperability of HRSN data and encourage the use of health IT-enabled assessment instruments with coded questions. We also refer readers to sections IX.E.5.b.(1).(g). where we discuss measure reporting. The MAP Health Equity Advisory Group majority voted that this measure has potential or high potential to have a positive impact by decreasing health disparities. The MAP Rural Health Workgroup majority voted agreement or strong agreement that this measure is suitable for use with rural providers.

On December 15, 2021, the MAP Hospital Workgroup reviewed the MUC List, including the Screening for Social Drivers (MUC21–136) measure. The MAP Hospital Workgroup discussion was similar to that of the MAP Health Equity Advisory Group and MAP Rural Health Workgroup, and ultimately voted to conditionally support the measure pending NQF endorsement. On January 19, 2022, the MAP Coordinating Committee reviewed the MUC List including the Screening for Social Drivers of Health (MUC21–136) measure and voted to uphold the MAP Hospital Workgroup recommendation of conditional support for rulemaking.[560]

We intend to submit this measure in future for NQF endorsement. We note that under section 1866(b)(3)(B)(viii)(IX)(aa) of the Act, each measure specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this this topic, and, therefore we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

Measure specifications for this measure are available on the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites).

(c) Cohort

The Screening for Social Drivers of Health measure assesses the total number of patients, aged 18 years and older, screened for social risk factors (specifically, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during a hospital inpatient stay. The measure cohort includes patients who are admitted to an inpatient hospital stay and are 18 years or older on the date of admission.

(d) Numerator

The numerator consists of the number of patients admitted to an inpatient hospital stay who are 18 years or older on the date of admission and are screened for all [561] of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety during their hospital inpatient stay.

(e) Denominator

The denominator consists of the number of patients who are admitted to a hospital inpatient stay and who are 18 years or older on the date of admission. The following patients will be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening during their inpatient stay and have no legal guardian or caregiver able to do so on the patient's behalf during their inpatient stay.

(f) Measure Calculation

The Screening for Social Drivers of Health measure will be calculated as the number of patients admitted to an inpatient hospital stay who are 18 years or older on the date of admission screened for all [562] five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) divided by the total number of patients 18 years or older on the date of admission admitted to the hospital.

(g) Data Submission and Reporting

We are finalizing voluntary reporting of the Screening for Social Drivers of Health measure beginning with the CY 2023 reporting period, followed by mandatory reporting on an annual basis beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

Due to variability across hospital settings and the populations they serve, we are allowing hospitals flexibility with selection of tools to screen patients for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Potential sources of these data could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys. Multiple screening tools exist and many hospitals already have screening tools integrated into their electronic health records (EHRs). We suggest hospitals refer to the Social Interventions Research and Evaluation Network (SIREN) website, for example, for comprehensive information about the most widely used HRSN screening tools.[563] [564] SIREN contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions.

We note that providers participating in the Hospital IQR Program must use certified EHR technology (CEHRT) that has been certified to the 2015 Edition of health IT certification criteria under the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program, and extraction of structured data from a certified EHR can make the data more accessible for utilization and submission for quality measurement reporting (86 FR 45383). Use of certified health IT can also support capture of HRSN information in an interoperable fashion so that this data can be shared across the care continuum to support coordinated care. For instance, in the 2020 ONC 21st Century Cures Act final rule, ONC adopted a new framework for the core data set which certified health IT products must exchange, called the United States Core Data for Interoperability (USCDI) (85 FR 25669). Version 2 of the USCDI, published in July 2021, included new data classes for social determinants of health (SDOH). These include standards to capture

[560] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.*

[561] In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28502), we stated ''one or all of the following five HRSNs.'' We have updated the preamble of the final rule in this instance to state ''all five HRSNs'' as per the measure specifications and in alignment with the language throughout the preamble.

[562] In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28502), we stated ''one or all of the following five HRSNs.'' We have updated the preamble of the final rule in this instance to state ''all five HRSNs'' as per the measure specifications and in alignment with the language throughout the preamble.

[563] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: *https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison.* Accessed January 18, 2021.

[564] The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on the social determinants of health and healthcare delivery.

SDOH Problems/Health Concerns, SDOH Interventions, SDOH Goals, and SDOH Assessments. ONC recently published USCDI Version 3, which maintains the SDOH elements in Version 2 while adding additional data elements.[565] While adoption of USCDI Version 2 is not a requirement for ONC Health IT Certification at this time, under ONC's Standards Version Advancement Process,[566] developers of certified health IT may upgrade their certified health IT products to USCDI Version 2 to support the availability of information about social drivers of health. Version 3 will also be considered under the SVAP process.

Additional stakeholder efforts are underway to expand capabilities to capture additional social determinants of health data elements include initiatives such as the Gravity Project [567] to identify and harmonize social risk factor data for interoperable electronic health information exchange. We note these various efforts and encourage use of tools that will meet information exchange standards and facility interoperability. We also encourage providers to identify and utilize tools that rely on standards-based approaches to data collection and utilization to support interoperability of these data.

Hospitals are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System (previously referred to as the QualityNet Secure Portal). We refer readers to section IX.E.10. of the preamble of this final rule (Form, Manner, and Timing of Quality Data Submission) for more details on our previously finalized data submission and deadline requirements across measure types, and specifically, section IX.E.10.i. for our data and submission requirements for structural measures.

We invited public comment on this proposal.

We note to readers that due to the complementary nature of the Screening for Social Drivers of Health and the Screen Positive Rate for Social Drivers of Health, most of the public comments received were indicated as applicable for both measures. We are summarizing and responding to those comments relevant to the Screening for Social Drivers of Health first and then providing a summary and responses to both measures afterwards. Comments specifically about the Screen Positive Rate for Social Drivers of Health measure are in the subsequent section.

Comment: Many commenters emphasized support for requiring screening and reporting for all five HRSN domains, including housing instability, food insecurity, transportation needs, utility difficulties, and interpersonal safety. A few commenters expressed support for the measure but requested that we confirm their understanding that the measure as specified requires hospitals to screen for all five HRSNs.

Response: We thank the commenters for their support and confirm that hospitals would screen for all five HRSN domains. We note that there were two instances in the preamble of the FY 2023 IPPS/LTCH PPS proposed rule in which we made a technical error by inconsistently stating screening for ''one or all'' of the five HRSNs (87 FR 28502 and 87 FR 28503; sections IX.E.7.b.(1).(d). and IX.E.7.b.(1).(f).). The language should have indicated that this measure requires screening for *all* five HRSNs as per the measure specifications that we referred to throughout the preamble of the proposed rule (87 FR 28497) and as reviewed as part of the MUC review process.[568] We have now updated and footnoted these two instances in the preamble of this final rule and clarify here that this measure requires that patients be screened for all five HRSNs.

Comment: Many commenters supported our proposal to adopt the Screening for Social Drivers of Health measure beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. Specifically, many commenters applauded this proposal as one of the first patient-centered quality measures that will allow health systems and care providers to use a data-driven approach to account for the impact of drivers of health on patient health outcomes and healthcare access, including illness complexity, variations in severity, and resource utilization. Several commenters expressed their belief that adoption of this measure, together with the Screen Positive Rate for Social Drivers of Health measure, will improve health outcomes and healthcare costs. Some commenters stated that adopting both Social Drivers of Health measures could lay the foundation for future policy initiatives that will increase equitable access to healthy foods, safe and affordable housing, safe physical environments, and affordable healthcare.

Response: We thank commenters for their support of the Screening for Social Drivers of Health measure. We appreciate all of the comments and interest in this important topic. Public input is very valuable in the continuing development of our health equity quality measurement efforts and broader commitment to health equity. We agree that this measure, in combination with the Screen Positive Rate for Social Drivers of Health measure, will be a significant first step towards addressing the role of HRSNs in improving health equity, one of our quality improvement goals.

Comment: Many commenters expressed support for the measure and applauded what they believe is a necessary step towards accounting for the role of drivers of health in persistent health disparities that perpetuate the health equity gap and inflate healthcare costs for populations that have been historically underserved. Many commenters supported the adoption of the measure, noting it would enable healthcare providers and other healthcare professionals to take a data-driven approach to identifying important social risk factors and unmet needs among under-resourced populations across settings. Several commenters referenced the role the COVID–19 pandemic has played in magnifying pre-existing disparities in drivers of health and their impact on health outcomes and healthcare access among historically underserved populations in the U.S. Some commenters identified specific opportunities for drivers of health data to enhance care continuity that is essential for under-resourced population groups. A commenter recommended we start drivers of health screening in vulnerable populations first.

Response: We thank the commenters for their support of the measure and the input shared on its utility. We agree with commenters that drivers of health data are a critical first step towards accounting for the profound influence these factors have on health outcomes, especially in patient groups that experienced the disproportionate effects of the COVID–19 pandemic, healthcare providers who deliver care to groups

[565] Office of the National Coordinator for Health IT. (2022). United States Core Data for Interoperability, Version 3 (July 2022). Available at: *https://www.healthit.gov/isa/sites/isa/files/2022-07/USCDI-Version-3-July-2022-Final.pdf.*

[566] Office of the National Coordinator for Health IT. (2022). Standards Version Advancement Process. Available at: *https://www.healthit.gov/topic/standards-version-advancement-process-svap.*

[567] See *https://thegravityproject.net/.*

[568] National Quality Forum. Measure Applications Partnership Hospital Workgroup (2021). Virtual Review Meeting Summary available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629.*

who have been historically underserved by the healthcare system, and ultimately, the costs associated with health disparities. We are committed to closing the health equity gap and this measure is a step towards that goal. The five HRSN domains are derived from a robust evidence base that has demonstrated over time both direct correlations between these drivers of health and patient outcomes and significant benefits associated with relevant interventions (87 FR 24898). We expect the data captured by this measure will inform meaningful and sustainable solutions for other provider-types through similar data collection in other quality reporting programs. While we appreciate the recommendation to address screening in populations who have been historically underserved by the healthcare system first, we believe national implementation of this measure in conjunction with the Screen Positive Rate for Social Drivers of Health measure will allow us to more accurately identify those hospital communities where there may be higher rates of patients who indicate one or more of the five HRSNs.

Comment: Several commenters supported our proposal, noting their belief that the measure will advance CMS' strategic pillars, specifically relative to advancing health equity. Some commenters viewed adoption of this measure as an initial, necessary, and logical outgrowth from CMS' strategic pillar around health equity because it will address the interactions between social conditions and health outcomes on a broad scale and facilitate true care continuity for patients experiencing the impact of drivers of health. Some commenters noted the measure presents opportunity for alignment across public and private quality performance measurement, potential to inform healthcare benefit design across systems of care and payment programs, and alignment with the CY 2023 Medicare Advantage and Part D rule and the Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) Model, both of which they note include requirements for including drivers of health in enrollee health risk assessments.

Response: We thank the commenters for their support and appreciate their input. We agree that drivers of health data will account for critical factors that impact patient outcomes and, consequently, quality performance. We believe HRSN screening will help healthcare professionals to explain the direct relationship between HRSNs and poor health outcomes and also strengthen collaboration between hospitals and community-based service providers. Further, we believe this data collection will inform meaningful and sustainable solutions for other provider types through similar collections in other quality reporting programs (87 FR 28501). We also agree that this measure aligns with proposals included in the CY 2023 Medicare Advantage and Part D rule (82 FR 27726) and the ACO REACH Model [569] as they both included proposals with a focus on inclusion of drivers of health and promotion of health equity.

Comment: Many commenters supported our proposal to adopt this measure, noting it would help support efforts to connect patients with relevant community resources, which in turn could interrupt the downstream effects of poor health outcomes and ultimately generate cost savings associated with healthcare delivery. Several commenters emphasized that adoption of the two Social Drivers of Health measures will support hospitals and health systems in addressing health disparities by encouraging meaningful collaboration with existing community-based organizations and guiding future public and private resource allocation to enhance these partnerships. Many commenters acknowledged that the measure data can be leveraged to support investments in and linkage to community resources; for example, building closed-loop referrals that link patients, healthcare providers, and community resources. A commenter identified community-based organizations and federally qualified health centers (FQHCs) as priority recipients of referral capacity-building resources from CMS. A commenter noted that the proposal will contribute to innovations in health and social care delivery.

Response: We thank the commenters for their feedback and support. We agree with commenters that availability of drivers of health quality data will potentially identify innovative opportunities to support enhanced availability of community resources to meet the needs identified by both these Social Drivers of Health quality measures. We share the commenters' belief that this measure could support efforts to connect patients in need with community resources.

Comment: Some commenters identified promotion and support for healthy aging as a potential benefit of adopting this measure. A few commenters described how the burdens experienced by patients with HRSNs often extend to caregivers. Some commenters expressed particular support for the emphasis this measure would place on food insecurity, given the direct association between food insecurity and chronic disease risk, healthcare utilization, and adverse health outcomes.

Response: We agree and thank the commenters for their support. We agree that HRSNs often extend to caregivers and other household members. We refer readers to our Caregiver Partners Workgroup which works to build bridges with caregiver organizations, both federal and non-federal, to better serve Americans in need with national and local resources to assist in their caregiving efforts.[570] We also refer readers to section IX.E.5.f. of the preamble of this final rule in which we discuss our proposal to adopt the Global Malnutrition Composite Score eCQM.

Comment: Many commenters noted that physicians are held clinically and financially accountable for patient outcomes without consideration of the extensive toll that HRSNs take on health outcomes over time. Several commenters believed the COVID–19 pandemic was instrumental in revealing the impact of health disparities on physician burnout, especially among providers who primarily deliver healthcare in communities that have been historically under-resourced. Several commenters supported our proposal to adopt the measure believing it could provide data that could be used to modify risk adjustment performance and payment standards to reflect more accurately the role of HRSNs in contributing to poor health outcomes and associated costs. A commenter described the dilemma of providing care to patients with significant unmet HRSNs and subsequent financial penalization for poor health outcomes as ''psychic risk'' that contributes to physician burnout. Some commenters noted their expectation that by facilitating investments in community resources, adoption of both Social Drivers of Health measures may reduce healthcare provider burden.

Response: We appreciate the commenters' feedback and acknowledge the burden that many healthcare providers experience in providing care to patients with significant drivers of health needs. Healthcare providers face

[569] Centers for Medicare & Medicaid Services. ACO REACH. (Accessed July 19, 2022). Available at: *https://innovation.cms.gov/innovation-models/aco-reach*.

[570] Centers for Medicare & Medicaid Services. (2022). Caregiver Partners. Available at: *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Caregiver*.

the challenges of trying to meet complex patient needs while being tasked with achieving quality performance standards that inevitably are impacted by their patients' unmet needs. We are committed to developing a better understanding of the role that drivers of health play in patient outcomes and hospital and physician quality performance. This measure is a first step towards achieving greater health equity and we recognize the central roles that hospitals and healthcare providers will continue to play in creating sustainable improvements in our quality programs.

Comment: Several commenters expressed support for the measure but requested we extend the proposed voluntary reporting period and delay mandatory reporting. Commenters cited a number of specific reasons, including: Operational complexity of developing new data collection and reporting protocols as well as revising workflows and training staff, ongoing constraints related to the COVID–19 PHE, and other resource limitation challenges such as addressing the numerous EHR-related reporting requirements. A commenter recommended we implement the measures over a longer period of time to ensure that resources to support health equity advancement result in improved health outcomes and avoid eroding patient trust in the healthcare system.

A commenter recommended further measure development prior to implementation to allow time for determination of data collection requirements. Several commenters did not support adoption of the measure, noting their belief that the CY 2024 reporting period/FY 2026 payment determination timeline for mandatory reporting would be too soon for generating reliable baseline data, and instead recommended extending the voluntary reporting period and delaying the mandatory reporting period. A commenter believed the proposed timeline for implementation will be inadequate for hospitals despite the proposed flexibilities.

Response: We thank the commenters for their support and feedback. We appreciate their concerns about the operational complexity of introducing drivers of health quality measures into existing clinical workflows and EHR systems. While we agree implementation of these two Social Drivers of Health measures will be a major undertaking for some providers, especially given the ongoing COVID–19 PHE, we also recognize that the COVID–19 PHE magnified the disproportionate burden of drivers of health on communities who have been historically under-resourced.[571] Beginning to collect the data remains imperative as we continue to build on our strategic pillar to advance health equity by addressing the health disparities that underlie our health system. We have therefore determined that the proposed voluntary and mandatory reporting periods prioritize the urgency of capturing drivers of health data and taking actionable steps towards closing the health equity gap. As stated in the proposed rule, potential sources of these data could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys (87 FR 28503). Additionally, we note that 92 percent of hospitals already screen for one or more of the five HRSNs—food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety—specified in the proposed measures (87 FR 28498). We believe that this is a strong indication that hospitals have processes in place to conduct the screening required.

Comment: A commenter recommended we require mandatory reporting without delay to encourage hospitals with existing screening capabilities to start data collection.

Response: We thank the commenter for this feedback. We believe the voluntary reporting period will be necessary for some hospitals as they integrate this measure specifications into their workflow. We encourage hospitals that already have such capacity and processes in place to initiate screening at the start of the voluntary period.

Comment: A few commenters supported the measure but recommended it not be included in the Hospital IQR Program. A commenter believed the measure would achieve its intended purpose in the Hospital Outpatient Quality Reporting (OQR) Program instead. A commenter was concerned about the inclusion of this structural measure in quality performance programs.

Response: We thank the commenters for their recommendation, but we respectfully disagree that the proposed measure is not suited for the Hospital IQR Program. We believe this measure, alongside the Screen Positive Rate for Social Drivers of Health measure, serves as a key first step in measuring and promoting quality improvement in the care delivered by hospitals in inpatient settings and will additionally encourage hospitals to collaborate with community-based organizations as part of discharge planning and implement closed-loop referrals that will more adequately address unmet social needs that drive hospital readmissions and diminished health outcomes following hospitalization. Given that individuals with high HRSNs also have greater healthcare needs that result in hospitalization, we believe the proposed Screening for Social Drivers of Health measure is appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings. Moreover, hospital accountability for screening is a critical step towards eliminating health disparities in health outcomes among populations that have been historically underserved by the healthcare system.

Comment: A commenter requested clarification of how hospitals will report the Screening for Social Drivers of Health data.

Response: We appreciate the commenter's request for clarification. In the proposed rule, we describe the measure specifications and data submission requirements, which can be found at *https://qualitynet.cms.gov/inpatient/iqr/resources* (87 FR 28502). Hospitals are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the HQR System (87 FR 28503). We also refer readers to section IX.E.10. of the preamble of this final rule (Form, Manner, and Timing of Quality Data Submission) for more details on our previously finalized data submission and deadline requirements across measure types, and specifically, section IX.E.10.i. for our data and submission requirements for structural measures.

Comment: Several commenters commented on our flexibility with screening tool selection. Several commenters supported this flexibility. Several commenters recommended we require hospitals take a standardized screening approach to implementing drivers of health assessments. A commenter believed that requiring standardized screenings would allow for more valid comparisons between hospitals.

A commenter supported the measure and emphasized the importance of allowing flexibility in screening tool selection until more is understood about data capture. A few commenters recommended we encourage hospitals to use validated, widely-accepted

[571] Centers for Disease Control and Prevention.(2020). CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.* Accessed November 17, 2021.

screening instruments to ensure data reliability and comparability to inform risk adjustment and further policy development. A commenter recommended we prioritize high-quality screening over volume of screening and track the number of patients who are linked to community-based resources to promote capacity-building for collaboration. A commenter recommended we clearly define screening to ensure active screening of drivers of health directly with the patient. Some commenters supported establishment of drivers of health screening but did not support the proposed approach of allowing hospitals flexibility with tool selection. A few commenters believed this flexibility will produce results that are not reliable and questioned whether there would be adequate denominator sizes to calculate reliable and valid comparisons.

Response: We appreciate all the commenters' support and input on the use of a screening tool. We share the enthusiasm of many of the commenters about the potential for improving quality of care and advancing health equity by addressing the unmet social needs of hospital patients. We agree that allowing hospitals flexibility with tool selection is a tradeoff, but, as we discussed previously, we believe it is necessary to allow hospitals flexibility because this measure is the first step in what we see as a longer journey to address unmet needs. This is the first time we will be collecting drivers of health screening data as part of quality performance measurement and we want to ensure that all hospitals are working towards initial screening, in a form that works for them. As we indicated previously, health equity is a key priority and we intend to continue to develop relevant measures. We recognize that hospitals often employ different strategies for screening for social needs across their patient populations. As such, in the FY 2023 IPPS/LTCH PPS proposed rule, we noted that hospitals pursuing this quality measure may use a self-selected screening instrument, which can vary to accommodate the population they serve and their individual needs, and that social needs data collected to satisfy this quality measure could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys (87 FR 28501). We also encouraged standards-based approaches to data collection and utilization to support interoperability of these data (87 FR 28503).

We are sensitive to the concerns raised by some commenters about the lack of standardization across screening instruments or data collection practices, and the challenges this may introduce in the consistency of the information collected across hospitals. While we acknowledge the potential benefits of a single screening instrument or prescribed set of standards, we also recognize the benefits of providing hospitals with flexibility to customize screening and data collection to their local community contexts and patient populations, especially in the initial stages of implementing screening protocols.

Currently, we intend to continue providing hospitals with flexibility regarding the selection of tools to screen patients. However, we anticipate additional emphasis on standardized and validated screening instruments in future versions of this measure. We encourage hospitals to prioritize screening tools that have undergone adequate testing to ensure they are accurate and reliable. We believe that this measure should promote high-quality screening practices which, among other things, ensure accurate identification of unmet social needs. We look forward to additional input from stakeholders on this topic.

We also recognize that digital data collection is a necessary path for effective and efficient measurement. As part of our Meaningful Measures 2.0 Framework [572] we aim to further shape the entire ecosystem of quality measures that promote innovation and modernization of all aspects of quality. A priority of the Meaningful Measure 2.0 Framework is transforming measures to improve quality measure efficiency by transitioning to digital measures and using advanced data analytics. We aim to transform to all digital quality measures, accelerate development of and testing electronic clinical quality measures using FHIR API technology for transmitting and receiving quality measurement, transform data collection to use FHIR API technology, and leverage centralized data analytic tools to examine programs and measures.

Currently, to the extent possible, we encourage hospitals to use certified health IT that can also support capture and exchange of drivers of health information in a structured and interoperable fashion so that these data can be shared across the care continuum to support coordinated care. We anticipate additional emphasis on data collection using certified health IT in future versions of this measure. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of this measure. We agree that allowing hospitals flexibility with tool selection is a tradeoff. This is the first time we will be collecting drivers of health screening data as part of quality performance measurement. We believe allowing hospitals flexibility during this initial first step will further enable them to adopt solutions that use structured EHR data elements to reflect patients' drivers of health status. We are taking commenters' recommendations under consideration to inform future notice-and-comment rulemaking.

We are taking commenters' recommendations under consideration to inform future notice-and-comment rulemaking.

Comment: Several commenters supported screening for drivers of health but expressed concerns regarding individual patient rights and transparency. A commenter recommended that patients be granted flexibility with timing of screening completion and adequate privacy is provided to the patient in the process. A commenter noted patients and families should be clearly informed that they can opt-out of screening and that their decision would not affect their care. A commenter recommended that the language and documentation of HRSNs in patient health records be non-stigmatizing and free of bias. Specifically, the commenter noted screening should not be included in hospital visit charges and that patients should be informed of the right to opt-out of screening. A commenter recommended we consider providing hospitals with comparative opt-out rates to provide benchmarks for individual hospitals to understand their own opt-out rates.

Response: We thank the commenters for their input. We underscore that patients and families will be able to opt-out of screening. Specifically, the measure specifications as proposed state that the following patients would be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening during their inpatient stay and have no legal guardian or caregiver able to do so on the patient's behalf during their inpatient stay (87 FR 28502). As discussed earlier, this measure does not require use of a specific screening tool. During measure development, we gave commenters' concerns significant consideration. As we noted in the FY 2023 IPPS/LTCH PPS proposed rule, we

[572] We note that Meaningful Measures 2.0 is still under development.

recommend that hospitals incorporate inclusive language in their screening activities to address this potential concern among patient and caregiver respondents (87 FR 28505). We strongly recommend that hospitals incorporate inclusive language in their screening activities to reassure patients that whether they choose to opt-out or answer the screenings, the information provided would not be used to stigmatize patients or reduce their healthcare benefits. We defer to hospitals to make the appropriate disclosures to their patients regarding how the collected data are used as well as ensuring that the patient and their caregiver(s) are informed of their option to opt-out of screening. Commenters' input is very valuable to our continuing development of health equity quality measurement and our aims to address the impact of HRSNs on healthcare access, utilization, outcomes, and costs.

Comment: A few commenters expressed concern regarding hospital staff training, recommending that staff members who conduct screening and follow-up on the results are adequately trained. A few commenters recommended delegating screening duties to frontline hospital workers who may have demographic congruence with patients.

Response: We thank the commenters for their input and agree that staff training on culturally sensitive engagement and trauma-centered care would be helpful. Throughout the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 25498 through 25504), we referred to the performance evaluation of the AHC Model which reported utilization of multiple staffing models that could be adapted to meet the specific workflow needs of participating providers, which allowed providers to optimize resources to complete screening, navigation, and reporting requirements.[573] AHC Model organizations developed and provided structured, systematic training for staff in screening, referral, and navigation roles.[574] Most used routine training approaches that included presentations (in person or online), experienced staff shadowing, role-playing of routine and challenging activities, staff performance reviews, and coaching. Quality was ensured through observing screening or navigation encounters, monitoring number of screenings completed, and tracking navigation follow-up. Many organizations also used innovative training strategies they believed were particularly effective. The training strategies included trauma-informed care, racial inequity and cultural competency training, motivational interviewing, and patient engagement.

Based on the experiences of AHC Model participating providers, we believe staff training is feasible, tools and resources are available, and the benefits of such trainings could apply beyond the activity of screening for HRSNs. As we discussed in the FY 2023 IPPS/LTCH PPS proposed rule, 92 percent of hospitals are already screening for one or more of the five HRSNs (87 FR 28498). And while only 24 percent are screening for all five HRSNs (87 FR 28498), we believe this data is a strong indication that screening is occurring in the inpatient hospital setting. We encourage hospitals to ensure staff are adequately trained to conduct screenings.

Comment: Some commenters expressed concerns about the timeline for screening in the hospital setting. A commenter requested clarification on whether screening must take place during each hospital admission, especially if screening has already been completed and data captured in the EHR during outpatient visits that occurred during the measure performance period. A few commenters noted that screening at the time of admission may not be feasible due to the patient's physical state and medical staff members' focus on stabilization. Some commenters noted screening may introduce undue burden to patients. A commenter recommended annual distinct patient screening. A few commenters recommended we permit hospitals to utilize drivers of health screening data previously documented in patient EHRs from care provided in ambulatory settings.

Response: We thank the commenters for their feedback, questions, and recommendations. We wish to clarify for stakeholders that screening should occur during the hospital stay as noted in the Cohort section of the preamble of the proposed rule in which we explain that the measure assesses the total number of patients 18 years and older, screened for social risk factors during a hospital inpatient stay (87 FR 28502). We refer readers to the Data Submission and Reporting section of the preamble of the proposed rule in which we explain that hospitals will have flexibility with screening and that potential sources of the drivers of health data could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys (87 FR 28503). For patients frequently admitted to the hospital due to chronic health conditions which are exacerbated by HRSNs, hospitals could confirm the current status of any previously reported drivers of health and inquire about others not previously reported. However, if this information has been captured in the EHR in the outpatient setting prior to repeat hospital admission, it could be included in hospital reporting of numerator and denominator data, during the performance measurement period. We will continue evaluating screening requirements in future notice-and-comment rulemaking.

Comment: Several commenters expressed support for the measure but recommended modifications and refinements related to the proposed five HRSN domains. Some commenters recommended adding more domains in addition to the five domains. A commenter suggested eight additional domains including financial strain, employment status, family and community support, education, physical activity, substance use, mental health, and disabilities. A commenter suggested we allow for optional reporting of additional domains to inform hospital discharge planning and facilitate linkages to community resources. A commenter questioned whether the utility difficulties domain would be redundant and better suited as a component of the housing instability domain. A few commenters recommended removal of the interpersonal safety domain due to uniquely sensitive considerations associated with interpersonal safety compared to the other four domains. A commenter recommended CMS not specify screening domains at all. A commenter believed health systems should be allowed to select additional non-essential domains and their own specific questions. A commenter expressed concern that hospitals might focus on domains and questions that align with existing resources that are already offered to patients with given HRSNs. A commenter supported the measure and recommended CMS prioritize collection of self-reported drivers of health data.

Response: We thank the commenters for their support and appreciate their acknowledgement of the relevance of other drivers of health that influence health outcomes and contribute to persistent health disparities. We have prioritized selection of the proposed five HRSN domains based on existing evidence from both the AHC Model, including recommendations from a TEP that informed the initial selection, and

[573] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[574] *Ibid.*

emerging evidence of correlations between given drivers of health and worse health outcomes and/or drivers of health for which interventions have shown marked improvements in health outcomes and healthcare utilization (87 FR 28498). We remind stakeholders that the proposed measure is a first step towards development of a long-term strategy to integrate drivers of health data into hospital quality performance measurement and our broader commitment to health equity. We believe it is imperative that hospitals screen for all five domains, irrespective of resource availability.

Additionally, regarding the concern that hospitals will focus on domains that align with their existing resources, we believe that each hospital best understands the patient population they serve. As they collect these data, we hope that they can then best discern whether they have existing resources to meet their populations' unmet needs or dedicate further resources to a domain beyond the five required HRSNs for which they knew a need exists and now have evidence of the extent that resource allocation is necessary. In addition, we highlight that the Hospital IQR Program is a pay-for-reporting program, and hospitals are not scored based on their performance on measures.

We thank the commenters for the additional domain suggestions and we will consider them as part of any potential future modifications to these measures or potential new measure development in future notice-and-comment rulemaking.

Comment: Several commenters expressed concern about the lack of current NQF endorsement of the proposed measure at the time of proposed rule display. A few commenters recommended we delay adoption of the measure until NQF endorsement is obtained.

Response: We have submitted this measure for NQF review and the decision is currently pending. Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies. We note that the MAP also voted to conditionally support this measure for rulemaking (87 FR 28502).

Comment: Several commenters recommended we use consistent terminology when describing social risk factors related to health outcomes.

Response: We thank the commenters for this feedback. HRSNs, which we have previously defined as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization (87 FR 28502). Conceptually, HRSNs exist along a continuum with other equity-related terms—such as ''social determinants of health'' and ''social risk factors''—used to describe upstream factors that can adversely affect the health of individuals and communities (87 FR 28497).[575] We agree these terms are often conflated and even used interchangeably, and the variety of terms has created both confusion as well as concern, prompting leaders in the field to adopt ''drivers of health'' instead.[576] In the future, we intend to utilize ''drivers of health'' terminology to more holistically capture aforementioned and related concepts, while minimizing potential misinterpretation or negative connotation.

Comment: Several commenters expressed concerns regarding follow-on resources not being readily available to address the drivers of health for which patients might screen positive. A few commenters noted screening should not occur for resources that are not easily obtained.

Response: We thank the commenters for their input and appreciate the concerns noted. During development of both proposed Social Drivers of Health measures, we gave this topic significant consideration. The intent of the two measures is to promote adoption of HRSNs screening by hospitals as well as taking action to connect patients who identify one or more HRSNs with available resources (87 FR 28501). Evaluation of the AHC Model concluded that universal screening may identify needs that would otherwise remain undetected.[577] While broad availability of community-based resources that address patients' health-related social needs would be ideal, we believe that one of the benefits of screening data will be identification of opportunities to enable meaningful action, including prioritizing and investing in such resources (87 FR 28505). Beginning to collect the data remains imperative and such data collection has already allowed some entities to reallocate resources to address particular HRSNs that disproportionately affect a given patient population or geographic region.[578]

As we noted in the FY 2023 IPPS/LTCH PPS proposed rule, this data collection could inform meaningful and sustainable solutions for other provider-types through similar collections in other quality reporting programs (87 FR 28501). We believe this input is very valuable in the continuing development of the CMS health equity quality measurement efforts and our aims to acknowledge the impact of HRSNs on healthcare access, utilization, outcomes, and costs. We will continue to take all concerns, comments, and suggestions into account for any potential future development and expansion of our health equity quality measurement efforts.

Comment: Several commenters recommended we ensure alignment with Project Gravity standards and promote interoperability standards for data collection. A few commenters expressed concerns about implementation due to existence of other CMS initiatives that address social drivers of health in patient assessments and that this can create duplicative performance measures, cause confusion, and waste resources. A commenter recommended harmonization of drivers of health assessment approaches between CMS and the National Committee for Quality Assurance (NCQA).

Response: We thank the commenters for this feedback. We believe this data collection will inform meaningful and sustainable solutions for other provider types through similar collections in other quality reporting programs (87 FR 28501). We will continue identifying opportunities for collaboration with other stakeholders to align drivers of health assessment across CMS

[575] Institute of Medicine 2014. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/18951. https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.*

[576] *https://www.healthaffairs.org/do/10.1377/forefront.20210429.335599/.*

[577] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[578] National Quality Forum (2022). Measure Applications Partnership. MAP 2021–2022 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

programs. We commend additional stakeholder efforts currently underway to expand capabilities to capture additional drivers of health data elements, including the Gravity Project.[579] We support harmonization of social risk factor data for interoperable electronic health information exchange that will meet information exchange standards (87 FR 28503).

We will continue building the overarching strategy for integrating social drivers of health screening into hospital quality improvement and future rulemaking, where appropriate. We note that hospitals and CAHs participating in the Hospital IQR and Medicare Promoting Interoperability Programs must use CEHRT that has been certified to the 2015 Edition of health IT certification criteria under the ONC Health IT Certification Program, and extraction of structured data from a certified EHR can make the data more accessible for utilization and submission for quality measurement reporting (86 FR 45383). Use of certified health IT can also support capture of HRSN information in an interoperable fashion so that these data can be shared across the care continuum to support coordinated care. We note these various efforts and encourage use of tools that will meet information exchange standards and facility interoperability (87 FR 28503). We also encourage providers to identify and utilize tools that rely on standards-based approaches to data collection and utilization to support interoperability of these data.

Comment: Several commenters recommended that we take an incremental approach to using the Screening for Social Drivers of Health measure data.

Response: We thank the commenters for their feedback and recommendations for an incremental approach. In the proposed rule, we stated that collecting these baseline data via this measure would be crucial in informing design of future measures (87 FR 28502). If we add any data use for risk adjustment of the measure, we would do so in future notice-and-comment rulemaking. As noted previously, it would be ideal if there were broad availability of community-based resources that address patients' HRSNs such that we could evaluate their impact on health outcomes. However, the COVID–19 PHE revealed the significant and disproportionate burden of drivers of health in historically underserved communities. We believe that one of the benefits of screening data will be identification of opportunities to enable meaningful action, including prioritizing and investing in such resources (87 FR 28505). We remain hopeful that these actions will enhance patient trust in the healthcare system and trustworthiness of the system itself.

Comment: A commenter requested that future public reporting and payment adjustments correlate with care delivered to avoid bias stemming from local community sociodemographic characteristics. A commenter recommended that instead of requiring low-resourced hospitals report on this measure (who may not be able to implement data collection and workflow requirements), that we consider incentivizing screening instead.

Response: We note that the Hospital IQR Program is a pay-for-reporting program, and hospitals' payments are not based on their performance on measures. We note that hospitals will receive credit for the reporting of their measure results regardless of patients' responses to the questions. We refer readers to section IX.E.5.b.(1).(g). of this final rule for information on the submission and reporting requirements for this measure and to section IX.B. for our request for information on the Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Reporting Programs.

Comment: A commenter stated that interpretation of the proposed measure is challenging due to the absence of a meaningful goal or benchmark for the measure. The commenter believed if a hospital reports very low positive screen rates, this may indicate very low HRSNs among the patient population, or, a high level of mistrust and discomfort of patients to disclose sensitive needs to clinical staff.

Response: We thank the commenter for this feedback, but we respectfully disagree. We refer readers to the Overview section in the preamble of the proposed rule where we state, the measure is intended to provide information to hospitals on the level of unmet social needs among patients served and the extent to which these factors impact quality measure performance in the hospital inpatient setting (87 FR 28505). The Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures are closely related but inform distinct measure results, meaning it would be possible for a hospital to have a high screening rate and a lower screen positive rate, or a low screening rate and higher screen positive rate, in one or more of the five domains.

Comment: Commenters offered recommendations for future consideration for our drivers of health strategy. A commenter recommended including the measure in other CMS quality performance programs including the Merit-based Incentive Payment System (MIPS) and Outpatient Quality Reporting programs, such as the Hospital OQR Program. A commenter recommended we conduct outreach with voluntary reporters to assess data collection processes and identify potential challenges and determine the extent to which the screening information supports health equity improvements. A commenter recommended we conduct outreach to hospitals to provide education on available screening methods.

Response: We thank the commenters for these recommendations and will consider their input. The Social Drivers of Health measures are the first of their kind in CMS quality programs. Through adoption of these measures in the Hospital IQR Program, we encourage hospitals to initiate screening if they have not already done so. In the CY 2023 Physician Fee Schedule proposed rule, we are also proposing to adopt the Screening for Social Drivers of Health measure for MIPS.[580] Further, we believe this data collection will inform meaningful and sustainable solutions for other provider types through similar collections in other quality reporting programs (87 FR 28501).

Comment: A commenter stated there was a lack of evidence to support a direct relationship between drivers of health screening and positive impact on hospital quality performance because this was not tested in the AHC Model.

Response: We appreciate the commenter's concern, but we respectfully disagree. The two Social Drivers of Health measures are derived from existing evidence from both the AHC Model [581] and emerging evidence of correlations between the designated drivers of health and higher healthcare utilization of emergency departments and hospitals, worse health outcomes and/or drivers of health for which interventions have shown marked improvements in health outcomes and health care utilization (87 FR 28498).

[579] *https://thegravityproject.net/.*

[580] Currently on display at: *https://www.federalregister.gov/public-inspection/2022-14562/medicare-and-medicaid-programs-calendar-year-2023-payment-policies-under-the-physician-fee-schedule.*

[581] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

After consideration of the public comments we received, we are finalizing our proposal as proposed.

(2) Screen Positive Rate for Social Drivers of Health Measure

(a) Background

The impact of social risk factors on health outcomes has been well-established in the literature.[582] [583] [584] [585] [586] The Physicians Foundation reported that 73 percent of the physician respondents to their annual survey agreed that social risk factors like housing instability and food insecurity would drive health services demand in 2021.[587] As noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28497 through 28506), recognizing the need for a more comprehensive approach to eliminating the health equity gap, we have prioritized development and implementation of quality measures that will capture social risk factors and facilitate assessment of their impact on health outcomes and disparities and healthcare utilization and costs.[588] [589] [590] Specifically, in the inpatient setting, we aim to identify patient HRSNs as part of discharge planning with the intention of promoting linkages with relevant community-based services that will address those needs and support improvements in health outcomes following hospitalization.

While the Screening for Social Drivers of Health process measure (discussed previously in section IX.E.5.b.(1).) enables identification of individuals with HRSNs, use of the Screen Positive Rate for Social Drivers of Health structural measure will allow us to estimate the impact of individual-level HRSNs on healthcare utilization, including hospitalizations, when evaluating quality of care.[591] [592] [593] The Screen Positive Rate for Social Drivers of Health structural measure will require the reporting of the resulting screen positive rates for each domain. Reporting the social drivers of health screen positive rate for each domain will inform actionable planning by hospitals towards closing health equity gaps and enable the development of individual patient action plans (including navigation and referral). We believe this effort could yield actionable information to close the health equity gap in CMS programs and policies.

In the FY 2022 IPPS/LTCH PPS final rule, we discussed ongoing consideration of potential approaches that could be implemented to address health equity through the Hospital IQR Program (85 FR 45414). As a result of the feedback we received, we identified the Screen Positive Rate for Social Drivers of Health measure to help inform efforts to address health equity. This structural measure assesses the percent of patients admitted to the hospital who are 18 years or older at time of admission who were screened for HRSNs and who screen positive for one or more of the core HRSNs, including food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety (reported as five separate rates).[594] We refer readers to section IX.E.5.b.(1).(a). of the preamble of this final rule where we previously discussed the CMS identification process resulting in the selection of these five domains.

The COVID–19 pandemic underscored the overwhelming impact that these five core domains have on disparities, health risk, healthcare access, and health outcomes, including premature mortality.[595] [596] Adoption of the Screen Positive Rate for Social Drivers of Health structural measure will encourage hospitals to track prevalence of specific HRSNs among patients over time and use the data to stratify risk as part of quality performance improvement efforts. This measure may also prove helpful for patients by providing data transparency and signifying hospitals' familiarity, expertise, and commitment regarding these issues. Evaluation of AHC Model participation demonstrated positive feedback and enhanced trust among patients.[597] This measure also has the potential to reduce healthcare provider burnout by systematically acknowledging patients' social needs that contribute to adverse health outcomes and linking providers with community-based organizations to enhance patient-centered treatment and discharge planning.[598] [599] [600] Finally, we

[582] Institute of Medicine 2014. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/18951.*

[583] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm.* Accessed November 23, 2021.

[584] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.* Accessed November 23, 2021.

[585] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016) The Association between Discrimination and the Health of Sikh Asian Indians. Health Psychology, 35(4), 351–355. *https://doi.org/10.1037/hea0000268.*

[586] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[587] The Physicians Foundation. (2020) 2020 Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.*

[588] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532.*

[589] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm.* Accessed November 23, 2021.

[590] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[591] Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: *https://doi.org/10.1377/hlthaff.2020.01742.*

[592] CMS. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm.* Accessed November 23, 2021.

[593] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752.*

[594] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[595] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.* Accessed November 23, 2021.

[596] Centers for Disease Control and Prevention. (2019). CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.* Accessed November 17, 2021.

[597] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[598] The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.*

[599] De Marchis, E., Knox, M., Hessler, D., Willard-Grace, R., Oliyawola, JN, et al. (2019). Physician Burnout and Higher Clinic Capacity to Address Patients' Social Needs. The Journal of the American Board of Family Medicine, 32 (1), 69–78.

Continued

believe there is a potential further value of this measure to facilitate data-informed collaboration with community-based services and targeted community investments, and enable quality improvement activities and efforts to address disparities, including the development of pathways and infrastructure to connect patients to community resources.

Underserved communities are disproportionately impacted by HRSNs, such as food insecurity, that impact health outcomes and cost.[601] [602] Unmet HRSNs have been directly associated with healthcare utilization, including hospitalization, especially for hospitals that serve such communities.[603] In pursuit of eliminating health equity gaps, we are focused on supporting effective and sustainable collaboration between healthcare delivery and community-based services organizations to meet the unmet needs of historically underserved populations. Reporting data from both the Screening for Social Drivers of Health measure and the proportion of admitted patients who screen positive for HRSNs across the five domains (via this complementary measure) will enable quantification of the levels of HRSNs in local communities served by a hospital and greater visibility into the interaction between HRSNs and health status, healthcare utilization, and quality of care. These measures harmonize, as it is important to know both if a hospital or health system is using a screening tool *and* the results from the screening. Ultimately, we believe that, together, these two social drivers of health measures could enhance collaboration to meet the needs of historically underserved populations by identifying high-risk individuals who will benefit from engagement with community-based service providers. As with the theory of change for the AHC Model, we would expect such collaboration, and associated increase in capacity and community investments, to yield a net reduction in costly healthcare utilization, such as ED visits and avoidable hospitalizations and promote more appropriate healthcare service consumption.[604]

Pursuant to Meaningful Measures 2.0, this measure addresses the ''healthcare equity'' priority area and aligns with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to ''develop and implement measures that reflect social and economic determinants.'' [605] Under CMS' Meaningful Measures Framework, the Screen Positive Rate for Social Drivers of Health structural measure addresses the quality priority of ''Work with Communities to Promote Best Practices of Healthy Living'' through the Meaningful Measures Area of ''Equity of Care.'' [606] Development of this measure also aligns with our strategic pillar to advance health equity by addressing the health disparities that underlie our health system.[607]

(b) Overview of Measure

The Screen Positive Rate for Social Drivers of Health structural measure is intended to enhance standardized data collection that can identify high-risk individuals who will benefit from connection via the hospital to targeted community-based services.[608] The measure will identify the proportion of patients who screened positive on the date of hospital admission for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. Hospitals will report this measure as five separate rates. We note that this measure is intended to provide information to hospitals on the level of unmet social needs among patients served, and not for comparison between hospitals.

The Screen Positive Rate for Social Drivers of Health (MUC21–134) measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List), a list of measures under consideration for use in various Medicare and Medicaid programs.[609] The MAP Rural Health Advisory Group and the Health Equity Advisory Group reviewed the measure on December 8, 2021, and December 9, 2021, respectively. Both groups expressed concerns about standardization of the measure and operationalization approaches that will yield real solutions for patients and clinicians. We intend to prioritize consideration of potential standardization approaches in future rulemaking. The MAP Health Equity Advisory Group members emphasized the importance of explaining to patients that self-report of HRSNs will not be used to stigmatize them or reduce healthcare benefits. We recommend that hospitals incorporate inclusive language in their screening activities to address this potential concern among patient and caregiver respondents. The measure developer stated that the focus of this measure is to establish standard social drivers of health screening measures, referencing data from the AHC Model as having demonstrated the feasibility of implementing HRSN screening and how essential the screening results are to enable action. Stakeholders' support for the measure was attributed, in part, to potential for hospitals, health systems, and community-based organizations to use the data to identify and prioritize opportunities for investment in community resources to address these HRSNs. Likewise, discussants reported that screening for HRSNs has allowed payors to enhance their understanding of the scope of such challenges among their patients, target resource investments, initiate changes in benefits designs, and prioritize community partnerships. We expect that hospitals will report similar findings and use the data to enhance resource allocation that will support referrals to relevant

[600] Kung, A., Cheung, T., Knox, M., Willard-Grace, R., Halpern, J., et.al, (2019). Capacity to Address Social Needs Affect Primary Care Clinician Burnout. Annals of Family Medicine. 17 (6), 487–494. Available at: *https://doi.org/10.1370/afm.2470.*

[601] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[602] U.S. Department of Agriculture Economic Research Service (2021). Food Security in the U.S. Accessed January 18, 2022. Available at: *https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/key-statistics-graphics.aspx.* Accessed January 18, 2022.

[603] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[604] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm.* Accessed November 23, 2021.

[605] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[606] Centers for Medicare & Medicaid Services. (2021). CMS Measures Management System Blueprint (Blueprint v 17.0). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.*

[607] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[608] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights (June 2021). Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.* Accessed November 23, 2021.

[609] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464.*

community-based services organizations.

On December 15, 2021, the MAP Hospital Workgroup met and reviewed the MUC List, including the Screen Positive Rate for Social Drivers of Health (MUC21–134) measure. Similar concerns and support as raised during the MAP Health Equity Advisory Group and MAP Rural Health Workgroup were also discussed during the MAP Hospital Workgroup meeting. The MAP Hospital Workgroup voted to conditionally support the measure for rulemaking pending NQF endorsement. On January 19, 2022, the MAP Coordinating Committee met and reviewed the MUC List including the Screen Positive Rate for Social Drivers of Health (MUC21–134) measure. The Coordinating Committee upheld the vote of the MAP Hospital Workgroup.[610]

We intend to submit this measure in future for NQF endorsement. We note that under section 1866 (b)(3)(B)(viii)(IX)(aa) of the Act, each measure specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

This measure (alongside the Screening for Social Drivers of Health) will be the first patient-level measurement of social drivers of health. We believe this is an important measure to include because of the connection between HRSNs and patient health. When patients are admitted to hospital for inpatient care, there is substantial opportunity to screen for HRSNs and include relevant community services referrals as part of discharge planning. Providers will be able to identify if patients have unmet health-related social needs and the rate will help gauge what percentage of the population they serve (who are screened) indicate they need help, by HRSN domain. We envision that hospitals could implement and assess their quality improvement efforts to address patients' unmet social needs such as by connecting admitted patients identified with unmet social needs to local community resources. These efforts could include referring patients to services available through the hospital or the community. The information from this structural measure may serve as a baseline in the future to assess the proportion of admitted patients whose unmet social needs were addressed by the hospital during the hospital stay to support safe discharge and improved health outcomes.

Measure specifications for this measure are available on the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites).

(c) Cohort

The Screen Positive Rate for Social Drivers of Health is a structural measure that provides information on the percent of patients admitted for an inpatient hospital stay and who are 18 years or older on the date of admission, were screened for an HRSN, and who screen positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety.

(d) Numerator

The numerator consists of the number of patients admitted for an inpatient hospital stay who are 18 years or older on the date of admission, who were screened for an HRSN, and who *screen positive* for having a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety.

(e) Denominator

The denominator consists of the number of patients admitted for an inpatient hospital stay who are 18 years or older on the date of admission and are *screened* for an HRSN (food insecurity, housing instability, transportation needs, utility difficulties and interpersonal safety) during their hospital inpatient stay. The following patients will be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening during their inpatient stay and have no caregiver able to do so on the patient's behalf during their inpatient stay.

(f) Measure Calculation

The result of this measure will be calculated as *five separate rates.* Each rate is derived from the number of patients admitted for an inpatient hospital stay and who are 18 years or older on the date of admission, screened for an HRSN, and who screen positive for each of the five HRSNs—food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety—divided by the total number of patients 18 years or older on the date of admission screened for all five HRSNs.

(g) Data Submission and Reporting

We are finalizing voluntary reporting of the Screen Positive Rate for Social Drivers of Health measure beginning with the CY 2023 reporting period, followed by mandatory reporting on an annual basis, beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

Hospitals are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the HQR System. We refer readers to section IX.E.10. (Form, Manner, and Timing of Quality Data Submission) of the preamble of this final rule for more details on our previously finalized data submission and deadline requirements across measure types, and specifically, section IX.E.10.i. for our data and submission requirements for structural measures.

We invited public comment on this proposal.

Comment: Many commenters supported the proposal to adopt the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. Those commenters agreed with our described rationale for the proposal. Commenters believed the Screen Positive Rate for Social Drivers of Health measure would advance CMS' strategic pillar to advance health equity by providing data about the impact of drivers of health on patients' health outcomes, health disparities, physician quality performance, and health care costs. Several commenters applauded the proposal of the first drivers of health measures in hospital quality performance measurement. A commenter referenced recent studies that have quantified the significant

[610] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.*

impact of drivers of health on physician performance and Medicare spending. A commenter referenced recent research reports of approximately 80 percent of health outcomes being directly associated with drivers of health and many physicians reporting that such factors influence patients' health and health outcomes. Several commenters stated the measure would improve healthcare transparency, promote data-driven community resource investments, and inform and strengthen quality improvement efforts addressing health equity.

Response: We thank commenters for their support of the measure and agree that it, in combination with the Screening for Social Drivers of Health measure, will be a first step towards addressing drivers of health to improve health equity, which is one of our strategic pillars.

Comment: Many commenters supported the measure because it would provide data needed to identify factors that perpetuate health disparities. A commenter stated the measure would provide data on key contributors to poor physical and mental health outcomes. A few commenters noted the measure would provide additional data on the specific drivers of health challenges faced by patients in complement to the Screening for Social Drivers of Health measure. A few commenters believed the measure would highlight variability in drivers of health prevalence across hospitals, thereby reflecting the challenges faced by hospitals that disproportionately serve patients with higher HRSN burden. Several commenters believed the measure would allow CMS to account for HRSNs in risk adjustment for quality performance scoring and support targeted quality improvement activities. A few commenters noted the measure would promote data transparency and build credibility for hospitals engaging in social drivers of health screening and intervention activities. A few commenters emphasized the measure would be person- or patient-level which will support enhanced evaluation of the economic implications of HRSNs on healthcare billing, risk adjustment, and cost benchmarks. A commenter noted the measure would be especially important for practicing physicians and their patients because it would accelerate quality improvement activities that address health disparities. A few commenters believed the measure would enable public and private institutions to make strategic investments that will strengthen capacity-building for addressing patients' HRSNs.

Response: We thank commenters for their support of the measure and the multiple ways in which the data could potentially be used to inform evidence-based decision making. We believe this measure is the next logical step after screening for HRSNs. We agree with commenters that data from the measure will contribute to efforts to close the health equity gap. Specifically, for the Hospital IQR Program, we recognize that drivers of health contribute significantly to unplanned hospital re-admissions and other patient outcomes in the hospital inpatient setting which impacts hospitals and healthcare providers that serve patients who are disproportionately burdened with unmet HRSNs. We intend for the two measures to encourage hospitals' accountability for addressing health disparities and, specifically, that the Screen Positive Rate for Social Drivers of Health will enable identification of specific unmet needs among patients.

Comment: Several commenters did not support adoption of the Screen Positive Rate for Social Drivers of Health measure. A commenter did not support adoption of the Screen Positive Rate for Social Drivers of Health measure because they believed the measure would be inappropriate for CMS quality measurement.

Response: We thank the commenters for their input, but respectfully disagree. The intent of both measures is to promote adoption of HRSN screening by hospitals as part of a larger long-term strategy to improve patient outcomes and eliminate health equity gaps in the hospital inpatient setting. We refer readers to the Overview section in the proposed rule (87 FR 28505) where we state that the measure is intended to provide information to hospitals on the level of unmet social needs among patients served. We also refer the reader to our definition of quality measures as noted in our Measure Management System.[611] We believe the Screen Positive Rate for Social Drivers of Health measure will function as tools to help us measure and quantify healthcare processes and patient outcomes in the hospital inpatient setting.

Comment: A few commenters stated the measure lacks comparability across hospitals.

Response: We thank the commenters for their input. We refer readers to the Overview section in the proposed rule where we state that the measure is intended to provide information to hospitals on the level of unmet social needs among patients served, and not for comparison between hospitals (87 FR 28505).

Comment: A few commenters believed the measure would be difficult to interpret. Specifically, a commenter believed the Screen Positive Rate for Social Drivers of Health measure interpretation would be extremely difficult because the denominator will not be specific to the numerator's drivers of health domains. A few commenters expressed concern about potential confusion among patients and unclear interpretation that could lead to data misuse.

Response: We thank the commenters for their input. We appreciate the concerns noted and we will take them into consideration for our future outreach efforts aimed at enhancing understanding of the measures and how the data will be used. We do not agree with the commenters that the measure may lack specificity or clarity or create confusion. We refer readers to the explanation of the measure specifications and specifically, the Measure Calculation section (IX. E.5.b.(2).(f).), in which we discuss the relationship between the numerator and denominator.

Comment: A few commenters stated the measure does not capture response to screening or whether intervention occurred and was effective.

Response: We thank the commenters for their input. We stated in the proposed rule that utilization of screening tools to identify the burden of unmet HRSNs can be a helpful first step in identifying necessary community partners connecting individuals to resources in their communities (87 FR 28500). The measure does not currently include measurement of intervention efficacy, and we will consider this in future rulemaking.

Comment: A commenter questioned the value of public reporting of the Screen Positive Rate for Social Drivers of Health measure data.

Response: We thank the commenter for their input. Collecting healthcare quality data related to social drivers can promote transparency in delivery of care by increasing involvement of leadership in healthcare quality improvement, increasing a sense of accountability, helping to focus organizational priorities and providing a means of delivering important healthcare information to patients. We believe this will be especially important as we advance the aims of our strategic pillar to improve health equity in general and address the disproportionate impact that drivers of health have on hospital quality performance for organizations

[611] *https://mmshub.cms.gov/about-quality/new-to-measures/what-is-a-measure.*

that serve patient populations with high HRSN levels.

Comment: Several commenters stated the proposed timeline for voluntary and mandatory reporting is inadequate. A commenter stated the work required to make the measures meaningful and establish effective workflows would take many years to develop.

Response: We thank the commenters for their feedback. We appreciate the concerns about the operational complexity of introducing drivers of health quality measures into existing clinical workflows. While the implementation of these two Social Drivers of Health measures may be a major undertaking for some providers, especially given the ongoing COVID–19 PHE, we also recognize that the COVID–19 PHE magnified the disproportionate burden of drivers of health on communities who have been historically under-resourced.[612] We have therefore determined that the proposed voluntary and mandatory reporting periods balance the time needed to implement these measures with the urgency of capturing drivers of health data and taking actionable steps towards closing the health equity gap. As stated in the proposed rule, potential sources of these data could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys (87 FR 28503). Additionally, we note that 92 percent of hospitals already screen for one or more of the five HRSNs—food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety—specified in the proposed measures (87 FR 28498). We believe that this is a strong indication that hospitals have processes in place to conduct the screening required.

Comment: A commenter identified inadequate measure design and lack of measure specification and testing to support adoption as challenges to implementation of the proposed measures; the commenter recommended an attestation-based data collection approach.

Response: We thank the commenters for their input. We respectfully disagree with the commenter that the measures lack specification and testing. We appreciate the concerns noted and we refer readers to the Overview of Measure section in the proposed rule (and section E.5.b.(2).(b). of this final rule) where we provide the measure specifications (87 FR 28506). Specifically, we explain the numerator, denominator, and measure calculation for both measures. Moreover, evidence from the AHC Model evaluation supports adoption of the measure as proposed because it demonstrated the ability of drivers of health screening to identify higher cost and utilization patients in the hospital inpatient setting. The measures were reviewed by the MAP Hospital Workgroup, MAP Health Equity Workgroup, and the MAP Rural Health Workgroup and all supported inclusion of the measures in the Hospital IQR Program. We expect this will advance efforts for hospitals to reduce unplanned readmission rates.

Comment: A commenter was concerned about the appropriateness of including the measure in the Hospital IQR Program. The commenter believed the measure is a hospital ''case-mix'' measure instead of a structural measure. The commenter believed the measure does not reflect hospital quality performance because hospitals are not resourced to address the problems identified in HRSN screening.

Response: We thank the commenter for this input. We define a structural quality measure, also known as a structure measure, in the CMS Measurement Management System Blueprint as a measure that ''assesses features of a healthcare organization or clinician relevant to its capacity to provide healthcare.'' [613] This is particularly relevant in the hospital patient setting where patients with high levels of HRSNs tend to have higher utilization and costs related to care delivery. While case mix reflects the diversity, complexity, and severity of patient illnesses treated at a given hospital, patients' HRSNs and the levels of unmet need among screened patients have not previously been measured or publicly reported on a national scale. Moreover, while HRSNs contribute to case mix components such as illness severity and complexity, our initial aim with these measures centers on using drivers of health screening to understand the precursors of patient illnesses and disparities in health outcomes over time. We aim to encourage hospitals to address patient-level HRSNs in care delivery because patient characteristics greatly influence healthcare organizations' and healthcare professionals' capacity to deliver healthcare. We emphasize that screening for and reporting of HRSN prevalence among patients are intended to be *initial steps* towards more robust accounting of the impact of HRSNs on patient health and related outcomes during and following hospitalization. Hospitals will not be expected to address the problems identified by screening but instead will be expected to facilitate linkage to community resources that can assist patients in meaningful ways.

Comment: A few commenters recommended against publicly reporting the data for this measure. A few commenters specifically recommended against reporting data on the Compare tool due to risk of misinterpretation by consumers. A few commenters were concerned that public reporting of the data might suggest that hospitals serving communities with high HRSNs are under-performing. A commenter believed that public reporting the data would discourage hospitals from screening patients with higher risk. A commenter recommended we ensure the measures are implemented consistently to allow fair comparisons across providers and regions due to differences in capacity for screening and making follow-on services available. Several commenters recommended we provide outreach and education to patients and providers to address the meaning, reasons, and interpretation of the measures. A commenter recommended developing guidance on effective education on the measures for patients and providers. A commenter recommended we evaluate the ability of consumers to interpret the measure rate(s) accurately.

Response: We appreciate the commenters' concerns. We wish to remind readers that the measure is intended to provide information to hospitals on the level of unmet need among their patients, and not for comparison between hospitals (87 FR 28505). We intend to conduct outreach and education in conjunction with public reporting of the data for the two Social Drivers of Health measures. We believe public reporting of healthcare quality data promotes transparency in the delivery of care by increasing the involvement of leadership in healthcare quality improvement, creating a sense of accountability, helping to focus organizational priorities, and providing a means of delivering important healthcare information to consumers.[614]

[612] Centers for Disease Control and Prevention. (2020). CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.* Accessed November 17, 2021.

[613] Centers for Medicare & Medicaid Services. Measure Management System (MMS): Glossary. Available at: *https://mmshub.cms.gov/glossary.* Accessed July 22, 2022.

[614] Centers for Medicare & Medicaid Services Quality Net. Public Reporting Overview. Available

Continued

We intend to conduct outreach and education with providers and patients to share information about the two Social Drivers of Health measures in conjunction with public reporting.

Comment: A commenter believed the name of the measure is misleading and recommending changing the name because patients may misinterpret ''screening positive'' as a positive event.

Response: We thank the commenter for their input about potential misinterpretation of the measure name. While we are not changing the measure name at this time, we appreciate this feedback and will consider it in outreach and education in conjunction with public reporting of the data and potential future development of this and other related measures.

Comment: A commenter recommended considering a minimum level of cross-cultural validation of the measures and/or demonstration of how community members and patients participated in domain prioritization.

Response: We appreciate the commenters recommendations. We will consider this input as part of future measure maintenance analyses as well as future policy development.

Comment: A commenter recommended modifying the measure so that in addition to capturing the five separate rates, one for each of the HRSN domains, the measure would ''drill down'' into sub-components to include three options for each: Screen positive, screen negative, and did not screen. A commenter recommended reconsideration of the measure specifications to reduce risk of small denominator sizes that would impede calculation and/or interpretation.

Response: We thank the commenter for their input. We will consider this input as part of future measure maintenance analyses as well as policy development.

Comment: A commenter recommended consolidating the two Screening for Social Drivers measures into a single measure and adding a component that would capture screening follow-up. The commenter believed that one single measure then could be stratified by whether an individual screened positive or negative.

Response: We thank the commenter for their input. We will consider this input as part of future measure maintenance analyses as well as policy development.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

c. Cesarean Birth eCQM Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination With Mandatory Reporting Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28506 through 28510), we proposed to adopt the Cesarean Birth eCQM as one of the eCQMs in the Hospital IQR Program measure set that hospitals can self-select to report for the CY 2023 reporting period/FY 2025 payment determination. We also proposed to make reporting of this eCQM mandatory beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

(1) Background

A Cesarean section (C-section) is the use of surgery to deliver a baby (or babies) in lieu of vaginal delivery. The procedure entails surgical and anesthesia risks and requires mothers to undergo several days of inpatient, post-operative recovery. A C-section may occur on an elective or nonelective basis.[615] Elective C-sections may be planned due to the presence of a complicating medical condition, abnormal positioning of the baby, or other medical indications.[616] Elective C-sections may also occur for non-medical reasons, including maternal preference (in consultation with their healthcare provider), local practice patterns, malpractice risk, or other factors.[617] [618] [619] C-sections that occur upon a mother's request are rare, but occur after consultation with a clinician.[620]

The total rate of (elective and nonelective) C-sections has risen in the U.S. since the 1990s.[621] C-sections accounted for 31.8 percent of U.S. live births in 2020,[622] and there is a considerable amount of variation in the rates based on U.S. region, state, and healthcare institution.[623] There is also substantial variability across races and ethnicities; the rate of C-sections is: 30.8 percent among Non-Hispanic White women, 36.3 percent among Black women, 28.8 percent among American Indian or Alaska Native women, 32.6 among Asian women, and 31.4 percent among Hispanic women.[624] U.S. practice guidelines have not indicated an optimal rate of C-section or an appropriate variance rate; while international studies suggest a preference for a lower range than current U.S. rates.[625] [626] [627]

When medically indicated, a C-section can effectively prevent maternal and neonatal morbidity and mortality.[628] However, clinicians and consensus groups agree that increased C-section rates have not improved overall perinatal outcomes and that C-sections are overused.[629] [630]

at: *https://qualitynet.cms.gov/inpatient/public-reporting/public-reporting.*

[615] National Quality Forum. Quality Measure PC–02 (Cesarean Birth). Available at: *https://www.qualityforum.org/QPS/0471.*

[616] Xu, X., Yan, J.Y., Chen, L.C. (2021). Risk factors and maternal-fetal outcomes of pregnancies complicated by pre-eclampsia, following cesarean section after a trial vaginal birth. Chin Med J (Engl). 2021;134(18):2249–2251. doi:10.1097/CM9.0000000000001452.

[617] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol. 2014 Mar;210(3):179–93. doi: 10.1016/j.ajog.2014.01.026.

[618] Schifrin BS, Cohen WR. (2013). The effect of malpractice claims on the use of caesarean section. Best Pract Res Clin Obstet Gynaecol. 2013 Apr;27(2):269–83. doi: 10.1016/j.bpobgyn.2012.10.004. Epub 2012 Dec 1. Review.

[619] Chen CS, Liu TC, Chen B, Lin CL. (2014). The failure of financial incentive? The seemingly inexorable rise of cesarean section. Soc Sci Med. 2014 Jan;101:47–51. doi: 10.1016/j.socscimed.2013.11.010. Epub 2013 Nov 15.

[620] Committee on Obstetric Practice. (2019) Cesarean Delivery on Maternal Request. The American College of Obstetricians and Gynecologists, 133(1). Available at: *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/01/cesarean-delivery-on-maternal-request.*

[621] Osterman, M.J.K., Martin, J.A. (2014). Trends in Low-risk Cesarean Delivery in the United States, 1990–2013. National Vital Statistics Reports, 63(6): 1–16.

[622] Hamilton, B.E., Martin, J.A., Osterman, M.J.K. (2020). Births: Provisional Data for 2020. National Vital Statistics Rapid Release, no 12. DOI: *https://doi.org/10.15620/cdc:104993.*

[623] Kozhimannil, K.B., Law, M.R. & Virnig, B.A. (2013). Cesarean delivery rates vary tenfold among US hospitals; reducing variation may address quality and cost issues. *Health Affairs,* 32(3): 527–35.

[624] Hamilton, B.E., Martin, J.A., Osterman, M.J.K. (2020). Births: Provisional Data for 2020. National Vital Statistics Rapid Release, no 12. DOI: *https://doi.org/10.15620/cdc:104993.*

[625] National Collaborating Centre for Women's and Children's Health. (2011). Caesarean Section: NICE Clinical Guideline (commissioned by the United Kingdom National Institute for Health and Clinical Excellence).

[626] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[627] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. Plos Med, 15(1): e1002494.

[628] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[629] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean

Additionally, low risk C-sections—defined as deliveries by nulliparous, term, or singleton vertex (NTSV) women—have seen an increase. ''Nulliparous'' women are those who have never given birth to a live baby but may have had a miscarriage, stillbirth, or elective abortion. They have a lower risk of maternal morbidity and mortality during vaginal birth than do women who have undergone a previous C-section.[631,632] ''Term'' indicates a term birth (that is on or after 37 weeks' gestation), which has better outcomes than a preterm birth, and ''singleton'' refers to the birth of a single child during one delivery. Vertex presentations, which are those where the child is positioned headfirst, carry less risk than breech or transverse presentations.[633] The rate of low-risk C-section deliveries also varies by race and ethnicity; low-risk C-section births in 2020 were: 24.9 percent among NTSV Non-Hispanic White women, 30.6 percent among NTSV Non-Hispanic Black women, 23.6 percent among NTSV American Indian or Alaska Native women, 27.7 percent among NTSV Asian women, and 25.2 percent among NTSV Hispanic women.[634] A majority of which are still higher than the Centers for Disease Control and Prevention's (CDC's) Healthy People 2020 goal to reduce C-section births among NTSV women to 23.9 percent by 2020.[635]

C-sections have higher morbidity and mortality (9.2 percent) than vaginal deliveries (8.6 percent).[636] Existing literature largely does not distinguish whether inferior outcomes derive from cause (higher-risk patients undergo C-section) or effect (surgery carries inherent risks due to anesthesia, bleeding, infection, post-operative recovery, etc.).[637] However, taking an aggregate view of multiple studies over time, it appears that C-sections carry a higher risk of subsequent miscarriage, placental abnormalities, and repeat C-section.[638] The rates of transfusions, ruptured uteri, unplanned hysterectomies, and intensive care unit (ICU) admissions are higher among women who deliver via C-section for the first time than those who deliver vaginally for the first time across all races and ethnicities. However, non-Hispanic Black women who deliver via C-section for the first time had the highest rates of uterine rupture and ICU admission compared with all other races and ethnicities.[639]

In terms of neonatal outcomes, C-sections have higher respiratory morbidity (1 percent to 4 percent) than vaginal births (<1 percent).[640] Again, it is unclear whether this is because of cause (high-risk fetuses are more likely to be delivered by C-section) or effect (surgery carries inherent risks due to anesthesia, bleeding, infection, post-operative recovery, etc.). The medical indications for a C-section entail broad provider discretion because of the need to: (1) Balance any conflicting medical conditions of mother versus fetus; and (2) balance the C-section against any other competing clinical considerations or external constraints (for example, availability of operation room, personnel, and/or blood). It should also be noted that reducing the rate of C-sections does not result in worse outcomes for the mother or newborn, with newborn complications even declining in some hospitals with significant C-section reductions.[641]

Furthermore, C-sections receive higher reimbursement than vaginal deliveries (typically about 50 percent more). The prevalence of non-medically indicated C-sections carries economic impacts because C-sections are more expensive than vaginal deliveries and may be accompanied by adverse outcomes and complications, which similarly have substantial cost implications.[642]

We believe this eCQM will help further our goal of addressing maternal health outcomes in the Hospital IQR Program. Currently, the Hospital IQR Program includes two measures that address improving maternal health: The Elective Delivery measure (PC–01) (77 FR 53530) and the Maternal Morbidity Structural measure (86 FR 45361 through 45365). However, neither of these measures directly address the factors contributing to maternal mortality, such as the high rates of C-sections in the U.S. We believe adopting measures like the Cesarean Birth eCQM presents unique opportunities for large-scale quality measurement and activities that can improve the short- and long-term health outcomes for mothers and children.[643] We also refer readers to section IX.E.5.d. of the preamble of this final rule, where we also finalized the adoption of the Severe Obstetric Complications eCQM as part of the Hospital IQR Program measure set.

In response to increases in low-risk C-sections, HHS has included a goal of reducing low-risk C-sections by 25 percent in the next five years as part of the Maternal Action Plan.[644] To build on the previously established HHS Maternal Health Action Plan, the Vice President's nationwide call to action to reduce maternal morbidity and mortality, and ongoing efforts with HHS and across the federal government,[645]

delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[630] National Collaborating Centre for Women's and Children's Health. (2011). Caesarean Section: NICE Clinical Guideline (commissioned by the United Kingdom National Institute for Health and Clinical Excellence).

[631] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[632] National Quality Forum. (2016). Perinatal and Reproductive Health 2015–2016 Final Report. Available at: *https://www.qualityforum.org/Publications/2016/12/Perinatal_and_Reproductive_Health_2015-2016_Final_Report.aspx*.

[633] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[634] Hamilton, B.E., Martin, J.A., Osterman, M.J.K. (2020). Births: Provisional Data for 2020. National Vital Statistics Rapid Release, no 12. DOI: *https://doi.org/10.15620/cdc:104993*.

[635] Centers for Disease Control and Prevention, Maternal Child and Infant Health. *Healthy People 2020*. Available at: *https://www.cdc.gov/nchs/data/hpdata2020/HP2020MCR-C26–MICH.pdf*.

[636] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[637] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. Plos Med, 15(1): e1002494.

[638] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. Plos Med, 15(1): e1002494.

[639] Curtin, S.C., Gregory, K.D., Korst, L.M., Uddin, S.F.G. (2015) Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data from the Birth Certificate, 2013. National Vital Statistics Reports. Volume 64, Number 4. Available at: *https://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_04.pdf*.

[640] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[641] Main, E.K., Chang, S.C., Cape, V., Sakowski, C. Smith, H., Vasher, J. (2019) Safety Assessment of a Large-Scale Improvement Collaborative to Reduce Nulliparous Cesarean Delivery Rates. Obstetrics & Gynecology, 133(4):613–623. doi: 10.1097/AOG.0000000000003109.

[642] Kozhimannil, K.B., Law, M.R. & Virnig, B.A. (2013). Cesarean delivery rates vary tenfold among US hospitals; reducing variation may address quality and cost issues. Health Affairs, 32(3): 527–35. doi: 10.1377/hlthaff.2012.1030.

[643] Department of Health and Human Services. (2020). Healthy Women, Healthy Pregnancies, Health Futures: Action Plan to Improve Maternal Health in America. Available at: *https://aspe.hhs.gov/sites/default/files/private/aspe-files/264076/healthy-women-healthy-pregnancies-healthy-future-action-plan_0.pdf*.

[644] Department of Health and Human Services. HHS Initiative to Improve Maternal Health. Available at: *https://aspe.hhs.gov/topics/public-health/hhs-initiative-improve-maternal-health*.

[645] Department of Health and Human Services. HHS Initiative to Improve Maternal Health. Available at: *https://aspe.hhs.gov/topics/public-health/hhs-initiative-improve-maternal-health*.

the Biden-Harris Administration seeks to use a whole-of-government approach for improving maternal health and advancing maternal health equity that reduces maternal mortality and morbidity, reduces persistent disparities, and among other activities, increases hospital participation in HHS-sponsored maternal health quality improvement initiatives. A critical focus is reducing existing disparities in maternal health outcomes across race, ethnicity, and geographic area. The Cesarean Birth eCQM is intended to facilitate safer patient care by assessing the rate of NTSV C-sections to ultimately reduce the occurrence of non-medically indicated C-sections, promoting adherence to recommended clinical guidelines, and encouraging hospitals to track and improve their practices of appropriate monitoring and maternity care delivery for pregnant and postpartum patients. The 2020 performance measurement data for the Cesarean Birth eCQM indicates a 27.5 percent average rate of C-section birth for NTSV women (across 15 hospitals, N=933). A group of subject matter experts for NQF noted that decreasing the rate of non-medically indicated C-sections can result in increased patient safety, decreased maternal and neonatal morbidity, and substantial savings in healthcare costs.[646] Additionally, considering that Non-Hispanic Black women have the highest rate of low-risk C-sections along with the highest rates of uterine ruptures and ICU admissions as a result of C-sections, reducing low-risk C-section rates could improve maternal health outcomes for this population in particular by reducing the excess maternal morbidity they experience.[647] [648] [649]

Under CMS' Meaningful Measures Framework,[650] the Cesarean Birth eCQM addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Healthcare Harm.'' [651] Additionally, pursuant to Meaningful Measures 2.0,[652] this measure addresses the ''Safety'' priority area and aligns with our commitment to a patient-centered approach in quality measurement to ensure that patients are safe and receive the highest quality care.[653] Finally, this measure aligns with our strategic priorities including the pillar to advance health equity by addressing the health disparities that underlie our health system.[654]

Therefore, in the proposed rule, we proposed the adoption of the Cesarean Birth eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination. As part of the currently finalized eCQM reporting and submission requirements, hospitals must report on three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing eCQM, for a total of four eCQMs (85 FR 58939). Hospitals may choose to report it as one of the three self-selected eCQMs for the CY 2023 reporting period/FY 2025 payment determination. After which, beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years, the Cesarean Birth eCQM would be required to be reported by all hospitals, except those hospitals that do not have an obstetrics department and do not perform deliveries. We also refer readers to section IX.E.10.e. of the preamble of this final rule for our policy to modify the eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination.

(2) Overview of Measure

This measure assesses the rate of NTSV pregnancies delivered via C-section. Determining the NTSV C-section rate permits a hospital to compare its outcomes to other hospitals while focusing only on the NTSV population which can impact the rates of first time and possibly subsequent C-section rates. We note that the NQF has endorsed the chart-abstracted form of this measure (PC–02: Cesarean Birth, NQF #0471) as a voluntary consensus standard since 2008 and continuously renewed its endorsement (most recently in 2020).[655] The Rural Health Workgroup of the NQF's MAP also identified the chart-abstracted version as a measure that holds particular relevance for rural hospitals, noting how important it is to focus on best practices in obstetric care in rural areas.[656] We acknowledge that there are instances where C-sections are medically indicated, and we emphasize that this measure is not intended to discourage practitioners from performing C-sections when they are medically indicated. We believe that assessing the rate of NTSV C-sections may ultimately reduce the occurrence of non-medically indicated C-sections. We encourage hospitals whose measure rates are higher than rates at other hospitals to explore and evaluate differences in the clinical management of women in labor.[657] Further, this measure will help ensure that the Hospital IQR Program includes measures which are applicable to rural hospitals.

The Cesarean Birth eCQM was included in a publicly available document entitled ''List of Measures Under Consideration for December 1, 2018'' (MUC List).[658] The MAP's Final Report on February 15, 2019

[646] National Quality Forum. (2008) Perinatal and Reproductive Health Project NQF #0471 PC–02 Cesarean Section: Measure Submission and Evaluation Worksheet 5.0. Available at: *https://www.qualityforum.org/Projects/n-r/Perinatal_Care_Endorsement_Maintenance_2011/0471.aspx*.

[647] Department of Health and Human Services. (2020). Healthy Women, Healthy Pregnancies, Health Futures: Action Plan to Improve Maternal Health in America. Available at: *https://aspe.hhs.gov/sites/default/files/private/aspe-files/264076/healthy-women-healthy-pregnancies-healthy-future-action-plan_0.pdf*.

[648] Curtin, S.C., Gregory, K.D., Korst, L.M., Uddin, S.F.G. (2015) Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data from the Birth Certificate, 2013. National Vital Statistics Reports. Volume 64, Number 4. *https://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_04.pdf*.

[649] Debbink, M.P. Ugwu, L.G. Grobman, W.A. et al. (2022) Racial and Ethnic Inequities in Cesarean Birth and Maternal Morbidity in a Low-Risk, Nulliparous Cohort. Obstetrics & Gynecology;139(1): 73–82. doi: 10.1097/AOG.0000000000004620.

[650] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

[651] CMS' Meaningful Measures Framework can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page*.

[652] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*. We note that Meaningful Measures 2.0 is still under development.

[653] Centers for Medicare & Medicaid Services. (2021) CMS Quality Measurement Action Plan. Available at: *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf*.

[654] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms*.

[655] National Quality Forum. Quality Measure PC–02 (Cesarean Birth). Available at: *https://www.qualityforum.org/QPS/0471*.

[656] National Quality Forum, Measure Applications Partnership. (2018). A Core Set of Rural-Relevant Measures and Measuring and Improving Access to Care: 2018 Recommendations from the MAP Rural Health Workgroup. Available at: *http://www.qualityforum.org/Publications/2018/08/MAP_Rural_Health_Final_Report_-_2018.aspx*.

[657] Centers for Medicare & Medicaid Services. (2015). Cesarean Birth (PC–02) Measure Public Comment Summary. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/PC-02-Public-Comment-Summary-Memo.pdf?msclkid=a582dfc0b52411ecbab8ba3255a5b678*.

[658] Centers for Medicare & Medicaid Services. (2018). List of Measures Under Consideration for December 1, 2018. Available at: *https://www.cms.gov/files/document/2018rmuc-list clearancerpt.pdf*.

conditionally supported the eCQM for rulemaking pending NQF evaluation and endorsement.[659] The MAP suggested further feasibility testing, consultation with multiple stakeholders, and examination of unintended consequences.

Given the importance of this measure, we sought stakeholder input on the potential future inclusion of this measure in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19491 through 19494). Many stakeholders supported inclusion of the measure, though some stakeholders shared similar concerns as the MAP (84 FR 42493 through 42496). Thereafter, the measure steward conducted further reliability and validity testing in 2021 and submitted the measure to the NQF for consideration of endorsement in Spring 2022. Given the additional testing performed and feedback provided, we proposed this measure in the proposed rule.

We also note that in 2020, the measure steward introduced the Cesarean Birth eCQM as one of the available eCQMs hospitals can choose for data submission to meet The Joint Commission's ORYX® requirements.[660] The ORYX initiative integrates performance measurement data into The Joint Commission's accreditation process.[661] Currently, we understand that The Joint Commission uses both the chart-abstracted (PC–02) and the eCQM versions. A total of 15 hospitals (representing 6 sites) submitted production data for one quarter of calendar year 2020. We note that the measure steward reached out to all 15 hospitals to recruit sites willing to participate in reliability testing on the data submitted. Seven hospitals (representing 2 sites) volunteered. One site is a system representing six hospitals. The seventh hospital is a stand-alone facility that uses a different EHR system. During the third quarter of 2021, feasibility scorecards were completed, and the feasibility rate was found to be 98 percent across the two EHR systems. Reliability and validity testing revealed the Cesarean Births eCQM to have a measure outcome agreement rate of 83.7 percent with a kappa score of .750 indicating substantial agreement. Overall, the data element agreement rate for all hospitals was 92.2 percent.

As mentioned previously, the NQF has endorsed the chart-abstracted form of this measure. Additionally, the measure steward submitted the eCQM to the NQF for consideration of endorsement during Spring 2022. We note that section 1866(b)(3)(B)(viii)(IX)(aa) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and note that while the chart-abstracted version is endorsed, we were unable to identify any other NQF-endorsed measures on this topic, and, therefore we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

The measure specifications for the Cesarean Birth eCQM can be found on the eCQI Resource Center website, available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

(3) Data Sources

The eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data and then submitted by hospitals to CMS.

(4) Measure Calculation

This eCQM assesses the rate of nulliparous women with a term, singleton baby in a vertex position delivered by C-section birth.[662] The eCQM uses one of the following: Nulliparous defined as Parity = 0, Gravidity = 0, or Preterm and Term both = 0. Parity is the number of completed pregnancies reaching 20 weeks gestation regardless of the number of fetuses or outcome of the pregnancy. Gravidity is the number of pregnancies, current and past, regardless of the pregnancy outcome. Preterm is less than 37 weeks and 0 days, and Term is greater than or equal to 37 weeks and 0 days using best Estimated Due Delivery (EDD).

(5) Outcome

The outcome of interest is the number of C-sections to NTSV women divided by all live, term (≥37 weeks gestation) singleton deliveries to NTSV women.

(6) Cohort

The cohort consists of all patients in the denominator: Nulliparous women with a singleton, vertex fetus at ≥37 weeks of gestation who deliver a liveborn infant. The cohort includes all pertinent patients regardless of payer (for example, Medicare, Medicaid, other public programs, private insurance, self-pay, or charity care) or admission source (for example, home, ED, nursing home, hospice, another hospital, or law enforcement).

(7) Numerator

The measure numerator consists of the subset of patients delivering by C-section.

(8) Denominator

The measure denominator consists of the number of nulliparous women with a singleton, vertex fetus at ≥37 weeks of gestation who deliver a liveborn infant.

(9) Exclusion Criteria

The measure excludes patients with abnormal presentations or placenta previa.

(10) Risk Adjustment

This measure is not currently risk adjusted. When developing the measure, the exclusion criteria were chosen to ensure that the focus population will be women with NTSV pregnancies. Nulliparous women are those experiencing their first birth. These women have a lower risk of maternal morbidity and mortality during a vaginal birth delivery than do women who have undergone a previous C-section.[663] The population of women in the denominator as a result of the exclusions allow the measure to focus on a more homogeneous group of women where the greatest improvement opportunity exists as evidenced by variation in rates of NTSV C-sections,

[659] National Quality Forum.(2019). Measure Applications Partnership, MAP 2019 Considerations for Implementing Measures in Federal Programs: Hospitals Final Report. Available at: *https://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx*.

[660] The Joint Commission. (2020). 2020 ORYX Performance Measure Reporting Requirements. Available at: *https://www.jointcommission.org/-/media/tjc/documents/measurement/oryx/cy2020-oryx-reporting-requirements_.pdf*.

[661] The Joint Commission. Accreditation-ORYX. Available at: *https://www.jointcommission.org/measurement/reporting/accreditation-oryx/*.

[662] The Joint Commission. (2021). eCQM Specifications 2022 Reporting Period. Available at: *https://www.jointcommission.org/-/media/tjc/documents/measurement/specification-manuals/2022-reporting-period/january-2022/ecqm_specifications_reportingperiod_2022.zip*.

[663] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

indicating clinical practice patterns may affect this rate.[664] Lowering the C-section rate in NTSV pregnancies is important because C-sections may carry a higher risk of subsequent miscarriage, placental abnormalities, and repeat C-section.[665] The rates of ruptured uteri, unplanned hysterectomies, and ICU admission are higher among women who deliver via C-section for the first time than those who deliver vaginally for the first time across all races and ethnicities. However, non-Hispanic Black women who deliver via C-section for the first time had the highest rates of uterine rupture and ICU admission compared with all other races.[666] Focusing on the NTSV population aligns with the measure intent to have a significant effect on cesarean birth rates. We believe this could encourage a decrease in C-section rates in the NTSV population, which will in turn have a meaningful impact on future pregnancies and maternal health. Including a comprehensive set of maternal medical exclusions will add data collection burdens without commensurate benefit.

(11) Data Submission and Reporting

We refer readers to: Section IX.E.10.e. of the preamble of this final rule for a discussion of our previously finalized eCQM reporting and submission policies; and section IX.E.13.b. for the public reporting of eCQM data. Additionally, we refer readers to section IX.E.10.e.(4). where we discuss the use of the zero denominator declarations and case threshold exemption policies for hospitals.

We also refer readers to four related proposals discussed in the preamble of this final rule: (1) Section IX.E.10.e. where we discuss modifications to our reporting and submission requirements for eCQMs, including a discussion of our policy to require hospitals to report on the Cesarean Birth eCQM; (2) section IX.E.5.d. for our policy to adopt the Severe Obstetric Complications eCQM; (3) section IX.H.10.a.(2).of the preamble of this final rule for a discussion of similar policies to adopt these two perinatal eCQMs in the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs); and (4) section IX.E.8. where we are establishing a publicly-reported hospital designation to capture the quality and safety of maternity care and other related activities in advancing maternal health equity.

We invited public comment on this proposal.

Comment: Many commenters supported adoption of the Cesarean Birth eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. Commenters agreed with our rationale in the preamble of the FY 2023 IPPS/LTCH PPS proposed rule and underscored their beliefs that the measure could support the provision of high- quality maternity care, that this data is necessary for addressing the maternal health crisis, and that the measure could lead to improved clinical practices. Additionally, a few commenters indicated that their support was tied to the measure's alignment with their state's or The Joint Commission's reporting practices.

Response: We thank the commenters for their support of the Cesarean Birth eCQM and agree that measure is in line with best practices for reducing low-risk C-sections. As we noted in the preamble of the FY 2023 IPPS/LTCH PPS proposed rule, we believe the measure addresses a key priority area and will further our goal of addressing maternal health outcomes in the Hospital IQR Program (87 FR 28507).

Comment: A few commenters supported the proposal, but recommended staggered implementation, extending the voluntary reporting period for an additional year, or making the measure voluntary permanently.

Response: We thank commenters for their input on the timeline of adoption and implementation of the Cesarean Birth eCQM. We believe adopting measures like the Cesarean Birth eCQM presents unique opportunities for large-scale quality measurement and activities that can improve the short- and long-term health outcomes for mothers and children (87 FR 28508). As a result, we believe the proposed timeline of inclusion of this eCQM into the Hospital IQR Program measure set beginning in CY 2023 reporting period/FY 2025 payment determination (in which hospitals can choose to self-select reporting of this measure) followed by mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years is sufficient for EHR vendors and hospitals to incorporate, adopt, and implement this measure.

Comment: A few commenters supported the proposal and recommended monitoring the measures in the future to track performance or to modify or expand the exclusion criteria as needed.

Response: We thank commenters for their support and agree that continued monitoring of the measures is important. We believe collecting data and reporting results will provide a critical baseline and we will monitor the data and any unintended consequences of the measure as part of standard measure maintenance.

Comment: A commenter supported the measure and requested clarification on how non-birthing hospitals would be affected by the adoption of this eCQM.

Response: We thank the commenter for their requested clarification on how hospitals which do not provide labor and delivery services would be affected. As stated in the FY 2023 IPPS/LTCH PPS proposed rule, the Cesarean Birth eCQM would be reported by all hospitals participating in the Hospital IQR Program, except those hospitals that do not have an obstetrics department and do not perform deliveries (87 FR 28507). We also refer readers to section IX.E.10.e.(4). of this final rule where we discuss the Hospital IQR Program's zero denominator declarations and case threshold exemption policies for eCQMs. Zero denominator declarations allow a hospital whose EHR is capable of reporting eCQM data to submit a zero in the denominator for the reporting of an eCQM if the hospital does not have patients that meet the denominator criteria of that hybrid measure (82 FR 38387). Similarly, the case threshold exemptions policy allows for a hospital with five or fewer inpatient discharges per quarter or 20 or fewer inpatient discharges per year in a given denominator declaration be exempted from reporting on that individual eCQM (82 FR 38387). We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387).

[664] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[665] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. Plos Med, 15(1): e1002494.

[666] Curtin, S.C., Gregory, K.D., Korst, L.M., Uddin, S.F.G. (2015) Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data from the Birth Certificate, 2013. National Vital Statistics Reports, 64(4). Available at: *https://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_04.pdf.*

Comment: Many commenters did not support the adoption of the Cesarean Birth eCQM. Several commenters believed the measure is misaligned with factors that contribute to negative outcomes, or that testing and validation of the eCQM has been insufficient to establish that the measure is appropriately aligned. Several commenters did not support the measure because it does not have NQF endorsement. A few commenters recommended the adoption of alternative measures which they believed would more appropriately align with the equity goal. A few commenters did not support the measure because they believed there is no ideal rate of C-sections. A commenter did not support because they believed that diverting natural birth from C-section begins earlier than when a patient seeks hospital labor and delivery services, which the measure does not capture.

Response: We thank the commenters for their input. As stated in the FY 2023 IPPS/LTCH PPS proposed rule, the NQF has endorsed the chart-abstracted version of this measure and the measure steward has submitted the eCQM to NQF for consideration of endorsement (87 FR 28509). We also note that section 1886(b)(3)(B)(viii)(IX)(bb) offers an exception in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity under contract under section 1890(a) of the Act, and the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and note that while the chart-abstracted measure is endorsed, we were unable to identify any other NQF-endorsed measures on this topic and therefore believe the exception at 1886(b)(3)(B)(viii)(IX)(bb) applies. Given the severity of the maternal morbidity crisis and as there are currently no NQF-endorsed measures that address Cesarean birth we believe it is important to implement this measure as soon as possible. We appreciate the suggestions of alternative measures and will consider them for potential future rulemaking.

Regarding commenter concerns about testing and validation, the measure steward conducted additional testing in 2021. The reliability and validity testing found the measure to have an overall data element agreement rate of 92.2 percent and we therefore believe the measure to be reliable and valid for use in the Hospital IQR Program. We believe that this measure serves as a key first step in measuring and promoting quality improvement in maternity care by encouraging hospitals to track their rate of low- risk C-sections and practices that may be contributing to trends in low-risk C-sections in the United States. While we agree that there is no ideal rate of low-risk C-sections, we noted in the FY 2023 IPPS/LTCH PPS proposed rule, the Cesarean Birth eCQM is intended to facilitate safer patient care by assessing the rate of NTSV C-sections to ultimately reduce the occurrence of non-medically indicated C-sections, promoting adherence to recommended clinical guidelines, and encouraging hospitals to track and improve their practices in caring for pregnant and postpartum patients (87 FR 28508). Additionally, we acknowledged that there are instances where C-sections are medically indicated and continue to emphasize that this measure is not intended to discourage practitioners from performing C-sections writ large (87 FR 28508). A group of subject matter experts for NQF noted that decreasing the rate of non-medically indicated C-sections can result in increased patient safety, decreased maternal and neonatal morbidity, and substantial savings in healthcare costs.[667]

Comment: A commenter did not support adoption and expressed concern that the time to implement the measure was insufficient.

Response: We thank the commenter for their input and respectfully disagree that the timeline for adoption is not appropriate. We emphasize that as proposed, hospitals may choose to report the Cesarean Birth eCQM as one of the three self-selected eCQMs for the CY 2023 reporting period/FY 2025 payment determination. After which, beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years, the Cesarean Birth eCQM would be required to be reported by all hospitals, except those hospitals that do not have an obstetrics department and do not perform deliveries. This timeline will allow hospitals at least one year to prepare and implement the measure before they are required to report it.

Comment: A few commenters did not support the proposal because they believed the exclusion criteria are not broad enough and should be risk adjusted. A few commenters did not support adoption of the measure because it does not distinguish between medically necessary and non-medically necessary procedures. A commenter requested that CMS clarify that the measure is not intended to discourage medically necessary C-sections.

Response: We thank the commenters for their input. While we agree that there are many ways to track data related to the C-section rate in the United States, and ultimately reduce excess non-medically indicated C-sections, the standards and comprehensiveness of initiatives can vary widely, and we do not believe broadening exclusion criteria or risk adjustment is necessary at this time. As we noted in the FY 2023 IPPS/LTCH PPS proposed rule, when developing the measure, the exclusion criteria were chosen to ensure that the focus population would be women with NTSV pregnancies (86 FR 28510). Barring the presence of other co-morbidities, such women often have a lower risk of maternal morbidity and mortality at the time of delivery than their counterparts who have undergone a previous C-section (87 FR 28510). As a result of the existing exclusion criteria, the population denominator allows the measure to focus on a more homogeneous group where the greatest improvement opportunity exists. As evidenced by variation in rates of NTSV C-sections, clinical practice patterns in particular may affect this rate (87 FR 28510). Lowering the C-section rate in NTSV pregnancies is important because C-sections may carry a higher risk of subsequent miscarriage, placental abnormalities, and repeat C-section (87 FR 28510). The rates of ruptured uteri, unplanned hysterectomies, and ICU admission are higher among women who deliver via C-section for the first time than those who deliver vaginally for the first time across all races and ethnicities (87 FR 28507). However, non-Hispanic Black women who deliver via C-section for the first time had the highest rates of uterine rupture and ICU admission compared with all other races.[668] Including a comprehensive set of maternal medical exclusions would add data collection burdens without commensurate benefit. Regarding commenters' concerns based on a lack of distinction between medically indicated and non-medically indicated procedures, the measure is designed to

[667] National Quality Forum. (2008) Perinatal and Reproductive Health Project NQF #0471 PC–02 Cesarean Section: Measure Submission and Evaluation Worksheet 5.0. Available at: *https://www.qualityforum.org/Projects/n-r/Perinatal_Care_Endorsement_Maintenance_2011/0471.aspx.*

[668] Curtin, S.C., Gregory, K.D., Korst, L.M., Uddin, S.F.G. (2015) Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data from the Birth Certificate, 2013. National Vital Statistics Reports, 64(4). Available at: *https://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_04.pdf.*

track C-section prevalence in the lowest-risk population, and we believe that any reduction in the rate will inherently overburden non-medically indicated C-sections.

Comment: A few commenters did not support the eCQM because they believed the chart-abstracted version of the measure was acceptable.

Response: We thank the commenters for their input. We note that the NQF has endorsed the chart-abstracted form of this measure (PC–02: Cesarean Birth, NQF #0471) as a voluntary consensus standard since 2008 and continuously renewed its endorsement (most recently in 2020) (87 FR 28508). Additionally, the measure steward introduced the Cesarean Birth eCQM as one of the available eCQMs hospitals can choose for data submission to meet The Joint Commission's ORYX® requirements (87 FR 28509). We believe that the proposal for use of the eCQM version continues our approach to collect data derived from EHRs and make progress toward a transition to fully digital measurement. We refer readers to section IX.C. of the preamble of this final rule—''Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs—Request for Information''—where we outlined and solicited comments on ongoing efforts to advance digital quality measurement.

Comment: Many commenters recommended delaying adoption of the measure because they requested we conduct additional testing for validity and reliability testing.

Response: We thank commenters for their input and feedback on this measure. As we noted in the FY 2023 IPPS/LTCH PPS proposed rule, the measure steward submitted the eCQM to the NQF for consideration of endorsement during Spring 2022 (87 FR 28509). As part of that process, it has gone through the Scientific Methods Panel and no major issues were raised around measure reliability. Regarding reliability concerns, we refer readers to the discussion in FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28509) and in section IX.E.5.c. of the preamble of this final rule where we discuss the validity and reliability testing which found that this measure has a measure outcome agreement rate of 83.7 percent with a kappa score of .750 indicating substantial agreement. Overall, the data element agreement rate for all hospitals was 92.2 percent. Additionally, the measure developer notes that the Cesarean Birth eCQM rates for the 13 hospitals who submitted both eCQM and chart-abstracted measure results to the measure developer for 2020 discharges were correlated. A correlation of 0.1–0.3 is considered weak, 0.3–0.5 is considered moderate, and over 0.5 is considered strong. The measure developer also clarified that the eCQM and the chart-based (NQF-endorsed) versions of the measure correlate at 0.88 which is strong and is statistically significant ($p<0.01$). Given the severity of the maternal morbidity crisis we believe it is important to implement this measure as soon as possible.

Comment: A few commenters suggested additions to the measure to increase alignment with the measure's goals. The comments included recommendations that the measure: (1) track efforts taken to eliminate disparities in maternal health outcomes; (2) track unexpected complications in term newborns; (3) data be disaggregated; (4) track how social drivers of health contribute to C-section rates; (5) exclusion criteria be broadened; and (6) be monitored closely to determine if the measure is tracking useful data.

Response: We thank commenters for their recommendations on changes to the measure specifications. We note the current scope of the exclusion criteria are selected based on the most up-to-date literature and then were rigorously tested by the measure steward. While we agree that there are many ways to track data related to the C-section rate in the United States, the standards and comprehensiveness of initiatives can vary widely. We will keep the recommendations in mind in the future if any changes to the eCQM are necessary as part of our regular measure maintenance. Regarding monitoring of the measure's impact, we note that, as with all Hospital IQR Program measures, we will monitor the data as part of the standard measure maintenance.

Comment: A commenter recommended that the specifications for the measure be published concurrently with the final rule.

Response: As part of notice-and-comment rulemaking, we publish measure specifications on a CMS website for interested parties to review. As we noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28509), measure specifications for eCQMs, including the Cesarean Birth eCQM, can be found on the eCQI Resource Center website, available at: *https://ecqi.healthit.gov*.

Comment: A commenter recommended that CMS clarify that the measure tracks all procedures, regardless of payer.

Response: As we noted in the FY 2023 IPPS/LTCH PPS proposed rule that the cohort includes all pertinent patients regardless of payer (87 FR 28509).

Comment: A few commenters expressed concerns about the consistency of performance data extraction from clinical data or patient charts or requested clarification on extracting data from clinical notes. Specifically, a commenter expressed concern that not all components of the proposed measure are identifiable using standard coding data.

Response: We thank the commenters for their feedback. We interpret the commenters to mean that they have concerns about extracting clinical data from paper charts or notes. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170) for our previously adopted eCQM file format requirements. Under these requirements, hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format as was previously required; (2) may use third parties to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from noncertified sources in order to then input these data into CEHRT for capture and reporting QRDA I files. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387). We encourage hospitals to continue to work with their EHR vendors to refine their processes optimally.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

d. Severe Obstetric Complications eCQM Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination With Mandatory Reporting Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28510 through 28515), we proposed to adopt the Severe Obstetric Complications eCQM as one of the eCQMs in the Hospital IQR Program measure set on which hospitals can self-select to report for the CY 2023 reporting period/FY 2025 payment determination. We also proposed to make reporting of this eCQM mandatory beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

(1) Background

Severe maternal morbidity (SMM) refers to unexpected outcomes due to complications at labor and delivery that result in significant consequences to a woman's health, and includes, but is not limited to, hemorrhage, embolism, severe hypertension, stroke, and other serious complications.[669] Despite the highest rate of spending on maternity care, totaling $1.4 billion dollars in FY 2021,[670] the U.S. ranks worse than most other developed nations in pregnancy-related deaths and the rate of SMM is continuing to steadily increase.[671] [672] As reported by the CDC, the overall rate of SMM increased almost 200 percent, from 49.5 per 10,000 delivery hospitalizations in 1993 to 144 per 10,000 delivery hospitalizations in 2014.[673] [674] [675] Increasing rates of SMM are resulting in increased healthcare costs, longer hospitalization stays, and short- and long-term negative outcomes to women's health.[676] [677] [678] [679]

Without proper treatment and awareness surrounding SMM, such complications can lead to mortality.[680] While partially attributed to changes in reporting standards, the maternal mortality rate has also risen in the U.S. from 17 deaths per 100,000 live births in 1990 to 26 deaths per 100,000 live births in 2015.[681] Recent maternal mortality data from 2018 reveal that 658 women died from pregnancy-related complications, resulting in a rate of 17.4 deaths per 100,000 live births, with 77 percent of the deaths attributed to direct obstetric causes like hemorrhage, preeclampsia, obstetric embolism, and other complications.[682] [683] Researchers have found that the presence of select maternal morbidities such as chronic hypertension, preeclampsia, and sepsis were strongly associated with increased odds of mortality at the time of delivery.[684] [685] Similar to maternal mortality, the existing literature on maternal morbidity indicates that a significant proportion of maternal morbidity is highly preventable.[686] Therefore, timely and appropriate treatment of maternal morbidities is imperative to prevent complications that can lead to maternal mortality.[687]

Additionally, racial and ethnic disparities are significant; non-Hispanic Black women are at considerably higher risk for developing these maternal complications than are non-Hispanic White women.[688] [689] Maternal death rate data indicate wide ethnic and racial gaps exist in maternal healthcare and outcomes. The maternal death rate for Black women is more than double that of White women—37.1 deaths per 100,000 live births compared to 14.7—and almost three times the rate compared to Hispanic women—11.8 deaths per 100,000 live births.[690]

As stated in the HHS Action Plan to Improve Maternal Health in America,[691] we are pursuing a vision for improving maternal health by focusing on: (1) Reducing maternal mortality, including disparities by race, ethnicity, and geography, in 5 years; (2) reducing SMM, including disparities by race and ethnicity, in five years; and (3) increasing hospital participation in HHS-sponsored maternal health quality improvement initiatives. As reflected in these goals, a critical focus of our maternal health efforts is reducing existing disparities in maternal health outcomes across race, ethnicity, and geographic area. This is further reflected in the Biden-Harris Administration's first ever Presidential Proclamation recognizing Black Maternal Health Week.[692] CMS is also interested in promoting policies that ensure Americans who live in rural areas have access to high quality care, particularly in the area of maternal health where residents in rural settings have a 9 percent greater probability of SMM and mortality, compared with urban residents.[693] Ultimately, driving the development and execution of evidence-based best practices in maternity care, improving overall maternal health, and closing the racial and ethnic disparity gaps in outcomes are among our

[669] Centers for Disease Control and Prevention. (2021). Severe Maternal Morbidity in the United States. Available at: *https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html*.

[670] Kaiser Family Foundation. (2021). The U.S. Government and Global Maternal and Child Health Efforts. Available at: *https://www.kff.org/global-health-policy/fact-sheet/the-u-s-government-and-global-maternal-and-child-health-efforts/*.

[671] Centers for Disease Control and Prevention. (2021). Severe Maternal Morbidity in the United States. Available at: *https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html*.

[672] Maternal Health Task Force. (2015). Maternal Health in the United States. Available at: *https://www.mhtf.org/topics/maternal-health-in-the-united-states/*.

[673] Centers for Disease Control and Prevention. (2021). Severe Maternal Morbidity in the United States. Available at: *https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html*.

[674] Leonard SA et al. (2019). Racial and ethnic disparities in severe maternal morbidity prevalence and trends. Annals of epidemiology. 2019;33:30–36.

[675] Petersen EE, Davis NL, Goodman D, et al. (2019). Vital signs: pregnancy-related deaths, United States, 2011–2015, and strategies for prevention, 13 states, 2013–2017. Morbidity and Mortality Weekly Report. 68(18):423.

[676] Vesco KK et al. (2020). Costs of Severe Maternal Morbidity During Pregnancy in U.S. Commercially Insured and Medicaid Populations: An Observational Study. Maternal and Child Health Journal,24(1):30–38.

[677] Chen HY, Chauhan SP, Blackwell SC. (2018). Severe Maternal Morbidity and Hospital Cost among Hospitalized Deliveries in the United States. Am J Perinatol. 2018 Nov;35(13):1287–1296. doi: 10.1055/s-0038–1649481. Epub 2018 May 3. PMID: 29723900.

[678] Lin, Ching-Ching Claire, et al. (2020). ''Rural–urban differences in delivery hospitalization costs by severe maternal morbidity status.'' Annals of Internal Medicine 173.11_Supplement: S59–S62.

[679] Premier Inc. (2019). Report 2: The Added Cost of Complications During and After Delivery. Available at: *https://explore.premierinc.com/Global/FileLib/Quick_Start_Cloud/19250_BudleofJoyReport_Report2_v7_digital.pdf*.

[680] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. American Journal of Obstetrics and Gynecology, 215(3):B17–B22.

[681] Maternal Health Task Force. (2015). Maternal Health in the United States. Available at: *https://www.mhtf.org/topics/maternal-health-in-the-united-states/*.

[682] Hoyert, D. L., & Miniño, A. M. (2020). Maternal mortality in the United States: changes in coding, publication, and data release, 2018.

[683] St Pierre A, Zaharatos J, Goodman D, Callaghan WM. Challenges and Opportunities in Identifying, Reviewing, and Preventing Maternal Deaths. Obstet Gynecol. 2018 Jan;131(1):138–142. doi: 10.1097/AOG.0000000000002417. PMID: 29215526; PMCID: PMC6511983.

[684] Campbell, K. H. et al. (2013). Maternal Morbidity and Risk of Death at Delivery Hospitalization. Obstetrics and Gynecology, 122(3): 627–633. Available at: *https://journals.lww.com/greenjournal/fulltext/2013/09000/Maternal_Morbidity_and_Risk_of_Death_at_Delivery.20.aspx*.

[685] Mocumbi, A. O., Sliwa, K., & Soma-Pillay, P. (2016). Medical disease as a cause of maternal mortality: the pre-imminence of cardiovascular pathology: review articles. Cardiovascular journal of Africa, 27(2), 84–88.

[686] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. American Journal of Obstetrics and Gynecology, 215(3): B17.

[687] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. American Journal of Obstetrics and Gynecology. 215(3): B17.

[688] Leonard, S.A., Main, E.K., Scott, K.A., Profit, J., & Carmichael, S.L. (2019). Racial and ethnic disparities in severe maternal morbidity prevalence and trends. Annals of epidemiology, 33, 30–36.

[689] Petersen, E.E. et al. (2019). Vital signs: pregnancy-related deaths, United States, 2011–2015, and strategies for prevention, 13 states, 2013–2017. Morbidity and Mortality Weekly Report, 68(18), 423.

[690] Centers for Disease Control and Prevention. (2020). First Data Released on Maternal Mortality in Over a Decade. Available at: *https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2020/202001_MMR.htm*.

[691] U.S. Department of Health and Human Services. Healthy Women, Healthy Pregnancies, Healthy Futures: Action Plan to Improve Maternal Health in America. Available at: *https://aspe.hhs.gov/sites/default/files/private/aspe-files/264076/healthy-women-healthy-pregnancies-healthy-future-action-plan_0.pdf*.

[692] White House. (2021). A Proclamation on Black Maternal Health Week. Available at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/04/13/a-proclamation-on-black-maternal-health-week-2021/*.

[693] Kozhimannil, K.B., Interrante, J.D., Henning-Smith, C., & Admon, L.K. (2019). Rural-urban differences in severe maternal morbidity and mortality in the US, 2007–15. Health affairs, 38(12), 2077–2085.

agency's top healthcare quality and safety goals.[694]

Currently, the Hospital IQR Program includes two measures that address improving maternal health: The Elective Delivery measure (PC–01) (77 FR 53530) and the Maternal Morbidity Structural measure (86 FR 45361 through 45365). In section IX.E.5.c. of the preamble of this final rule, we are finalizing the adoption of the Cesarean Birth eCQM as part of the Hospital IQR Program measure set. However, there are currently no maternal morbidity or obstetric complications outcome-based measures in the Hospital IQR Program.

The Severe Obstetric Complications eCQM has been developed to focus on the high maternal morbidity and mortality rates in the U.S., which we believe will present important opportunities for large-scale quality measurement and improvement activities in the Hospital IQR Program.[695] Statistics on preventability vary but suggest that a considerable proportion of maternal morbidity and mortality events could be prevented.[696] [697] This measure is intended to facilitate safer patient care by increasing awareness of the danger of obstetric complications, promoting adherence to recommended clinical guidelines, and encouraging hospitals to track and improve their practices of appropriate monitoring and care delivery for pregnant and postpartum patients.

Under CMS' Meaningful Measures Framework, the Severe Obstetric Complications eCQM addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Healthcare Harm.'' Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''Safety'' priority area and aligns with our commitment to a patient-centered approach in quality measurement to ensure that patients are safe and receive the highest quality care.[698]

Therefore, in the proposed rule, we proposed the adoption of the Severe Obstetric Complications eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination. We previously finalized that hospitals must report on three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing eCQM, for a total of four eCQMs in the CY 2023 reporting period/FY 2025 payment determination (85 FR 58939). In the proposed rule, we proposed to include this measure as part of the measure set in the Hospital IQR Program which hospitals will be able to self-select for the CY 2023 reporting period/FY 2025 payment determination. After which, beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years, we proposed to require reporting of the Severe Obstetric Complications eCQM by all hospitals except those hospitals that do not perform deliveries or have an obstetrics department. We refer readers to section IX.E.10.e. of preamble of this final rule for our related policy to modify the eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination.

(2) Overview of Measure

This measure assesses the proportion of patients with severe obstetric complications which occur during the inpatient delivery hospitalization. The Severe Obstetric Complications eCQM was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List).[699] The MAP Rural Health Advisory Group reviewed the MUC List and the Severe Obstetric Complications eCQM (MUC 2021–104) on December 8, 2021.[700] The MAP Rural Health Advisory Workgroup discussed questions regarding the specifications of the measure. First, there was discussion about the use of blood transfusions as an intervention and concern that blood transfusions would be excluded and/or delayed when clinical evidence indicates that patients would benefit from transfusions as an earlier intervention. The measure developer provided clarification that this measure reports two outcomes, one that includes all patients that meet the numerator criteria, and one that excludes patients whose only qualification for the numerator is a transfusion.[701] This is as a recognition that transfusions may be necessary for a number of reasons and for less severe complications. Second, the MAP Rural Health Advisory Workgroup discussed that rural settings have high maternal morbidity and mortality and that this measure would help improve maternal health outcomes, and that since the measure is risk adjusted for the presence of economic/housing instability the measure has a focus on accounting for potential disparities. The measure developer added that as an EHR-based measure, these data are patient-specific and the measure was tested in both rural and urban settings.[702] The Workgroup voted majority support in agreement of the applicability of the Severe Obstetric Complications eCQM to rural health settings.[703]

The Severe Obstetric Complications eCQM (MUC2021–104) was also reviewed by the NQF MAP Hospital Workgroup on December 15, 2021, and received conditional support pending NQF endorsement.[704] Some MAP stakeholders expressed concerns about the minimum sample size and low case volumes as well as the risk adjustment methodology. The measure developer underscored for the MAP that this measure was tested in ten health systems which represented 28 hospitals and tested over 60,000 delivery encounters, and there was no concern

[694] Centers for Medicare & Medicaid Services. (2021). Evidence-based best practices for hospitals in managing obstetric emergencies and other key contributors to maternal health disparities. Available at: *https://www.cms.gov/files/document/qso-22-05-hospitals.pdf*.

[695] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698*.

[696] Davis, N.L., Smoots, A.N., & Goodman, D.A. (2019). Pregnancy-Related Deaths: Data from 14 US Maternal Mortality Review Committees. Education, 40(36), 8–2.

[697] Geller SE, Rosenberg D, Cox SM, et al. (2004). The continuum of maternal morbidity and mortality: factors associated with severity. American journal of obstetrics and gynecology, 191(3):939–944.

[698] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*. We note that Meaningful Measures 2.0 is still under development.

[699] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464*.

[700] National Quality Forum. (2022). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571*.

[701] National Quality Forum. (2022). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571*.

[702] National Quality Forum. (2022). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571*.

[703] National Quality Forum. (2022). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571*.

[704] National Quality Forum. (2022). Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care: Final Report. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

about case volumes.[705] The measure developer also clarified that testing was underway to evaluate the ideal risk adjustment methodology to determine approaches that would consider stratification based on sociodemographic factors, such as race and ethnicity, pre- and post-risk adjustment. We emphasized the importance of this measure and its role in helping hospitals to understand the disparities existent in maternal health outcomes.[706] Ultimately, MAP Hospital Workgroup stakeholders supported this measure and recommended conditional support because it would assist in surveillance on maternal morbidity, a clinical area that needs further measurement.[707] The MAP Coordinating Committee, which provides direction to the MAP workgroups, reviewed the Severe Obstetric Complications eCQM (MUC2021–104) on January 19, 2022, and voted to uphold the MAP Hospital Workgroup recommendation for conditional support pending NQF endorsement.[708]

In January 2022, the Severe Obstetric Complications eCQM was submitted for endorsement by NQF, and is currently under review. We note that section 1866(b)(3)(B)(viii)(IX)(aa) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

To evaluate the validity, feasibility, and reliability of the measure, in 2021, the measure developer, conducted pilot testing in a total of 10 sites, consisting of 28 hospitals. The measure developer conducted alpha testing (formative testing)[709] and beta testing (field testing)[710] on the measure. Feasibility testing was conducted to assess data collection and accessibility, and included nine sites in the analysis, which consisted of 27 hospitals and three different EHR systems.[711] Using NQF's eCQM Feasibility Scorecard template,[712] the measure developer calculated results which indicated high feasibility of data elements defining the measure specifications (98 percent), clinical and documentation workflows compared to measure intent (99 percent), data element availability (95 percent) and accuracy (98 percent), and use of data standards (96 percent).

Following feasibility testing, one site representing two hospitals withdrew from the project, one site representing one hospital was unable to submit beta testing data in the timeline requested, and one site representing one hospital was added; as a result, the measure developer conducted beta testing in eight healthcare test sites and 25 hospitals, representing three different EHR systems. The measure developer pulled data for delivery hospital encounters discharged from January 1 to December 31, 2020. During measure testing, the measure score reliability was assessed, which is the degree to which repeated measurements of the same entity agree with each other.[713] The measure developer estimated the measure score reliability using a signal-to-noise ratio to assess the values according to conventional standards. They assessed signal-to-noise reliability that describes how well the measure can distinguish the performance of one hospital from another. The signal is the proportion of the variability in measured performance that can be explained by real differences in performance. Scores can range from zero to one, where a score of zero implies that all the variability in a measure is attributable to measurement error, and a score of one implies that all the variability is attributable to real difference in performance. The reliability analysis yielded a median reliability score of 0.991 (range: 0.983–0.997) for any severe obstetric complication and 0.957 (range: 0.918–0.984) for severe obstetric complications excluding blood transfusion-only cases.

The measure developer completed validity testing on six sites representing 15 hospitals, which was a statistically relevant sample of electronically submitted inpatient encounters selected for re-abstraction for reliability testing and clinical adjudication from six of the beta testing sites. Validity testing of the measure refers to the correctness of conclusions about the quality of measured entities that can be made based on the measure scores (that is a higher score on a quality measure reflects higher quality).[714] Overall, the data element agreement rate for all six sites was 90.4 percent. Further, validity testing of the measure showed a performance score agreement rate of 91.2 percent with a kappa score of .881 indicating good agreement. Measure score validity testing revealed a high positive predictive value (rate of agreement) of 94.7 percent, and a

[705] National Quality Forum. (2022). Meeting Transcript—Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96632*.

[706] National Quality Forum. (2022). Meeting Transcript—Virtual Review Meeting. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96632*.

[707] National Quality Forum. (2022). Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care: Final Report. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

[708] National Quality Forum. (2022). Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care: Final Report. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

[709] Centers for Medicare & Medicaid Services. (2018). Alpha tests include methods to determine if individual data elements are available and if the form in which they exist is consistent with the intent of the measure. Measure Testing NMS Newsletter. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Measure_Testing_MMS_Newsletter_April_2018.pdf*.

[710] Centers for Medicare & Medicaid Services. (2018). Beta tests serve as the primary means to assess scientific acceptability and usability of a measure including gathering further information about feasibility. Measure Testing NMS Newsletter. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Measure_Testing_MMS_Newsletter_April_2018.pdf*.

[711] Centers for Medicare & Medicaid Services. (2018). eCQM Feasibility: How Stakeholders Inform Measure Development. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/eCQM-Feasibility.pdf*.

[712] National Quality Forum. (2022). NQF eCQM Feasibility Scorecard. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89036*.

[713] Centers for Medicare & Medicaid Services. (2018). CMS Measures Management System (MNS) Testing Scientific Acceptability for de novo eCQMS. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/CMS-MMS-Webinar-BP101-%E2%80%93-Scientific-Acceptability-of-eCQMs.pptx*.

[714] National Quality Forum. (2011). Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties. Available at: *http://www.qualityforum.org/Measuring_Performance/Improving_NQF_Process/Measure_Testing_Task_Force_Final_Report.aspx#:~:text=Validity%20of%20the%20measure%20score,quality%20measure%20reflects%20higher%20quality*.

negative predictive value of 100 percent. Likewise, sensitivity (responsiveness to change) and specificity (accuracy) across test sites for the measure score were high, at 100 percent and 90.5 percent, respectively.

The measure developer conducted testing of the Severe Obstetric Complications eCQM and found that across 60,184 delivery encounters at 8 different sites, the current observed rate of any severe obstetric complications was 244 and the mean risk-standardized rate across test sites was 247 (per 10,000 delivery hospitalizations). The severe obstetric complications rate excluding blood transfusion-only cases was 50 for both the observed rate and the mean risk-standardized rate across test sites (per 10,000 delivery hospitalizations). Through rigorous testing, the measure developer found that the measure was feasible, reliable, and valid.

The measure specifications for the Severe Obstetric Complications eCQM can be found on the eCQI Resource Center website, available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

(3) Data Sources

The eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data and then submitted by hospitals to CMS.

(4) Outcome

The outcome of interest (numerator) for the Severe Obstetric Complications eCQM is the number of inpatient hospitalizations for patients with severe obstetric complications occurring during the delivery hospitalization, not present on admission, which include the following: Severe maternal morbidity *diagnoses* (we refer readers to the subsequent table); severe maternal morbidity *procedures,* including blood transfusion, conversion of cardiac rhythm, hysterectomy, temporary tracheostomy, and ventilation; or a discharge disposition of expired.[715] [716] Table IX.E–03. summarizes the severe maternal morbidity categories along with their corresponding diagnoses:

TABLE IX.E-03. SEVERE MATERNAL MORBIDITY DIAGNOSIS SPECIFIED IN THE NUMERATOR DEFINITION

Severe Maternal Morbidity Diagnoses Category	Severe Maternal Morbidity Diagnoses
Cardiac	Acute heart failure
	Acute myocardial infarction
	Aortic aneurysm
	Cardiac arrest/ventricular fibrillation
	Heart failure/arrest during procedure or surgery
Hemorrhage	Disseminated intravascular coagulation
	Shock
Renal	Acute renal failure
Respiratory	Adult respiratory distress syndrome
	Pulmonary edema
Sepsis	Sepsis
Other Obstetric Complications (OB)	Air and thrombotic embolism
	Amniotic fluid embolism
	Eclampsia
	Severe anesthesia complications
Other Medical Complications	Puerperal cerebrovascular disease
	Sickle cell disease with crisis

This measure is intended to report two outcomes: (1) Severe obstetric complications; and (2) severe obstetric complications, but excluding delivery hospitalizations for which blood transfusion was the only numerator event.

(5) Cohort

The measure cohort (denominator) consists of inpatient hospitalizations for patients between eight years of age and less than 65 years of age admitted to the hospital for inpatient acute care who undergo a delivery procedure for a stillbirth or livebirth greater than or equal to 20 weeks' gestation, with a discharge date that ends during the measurement period. Patients with confirmed diagnosis of COVID–19 with COVID–19-related respiratory condition or patients with confirmed diagnosis of COVID–19-related respiratory procedure are excluded from the measure calculation.[717]

(6) Risk Adjustment

The Severe Obstetric Complications eCQM is a risk-adjusted measure. The measure developer identified candidate risk variables for severe obstetric complications for consideration in the measure risk adjustment model by utilizing literature and research findings, consulting with an expert clinical consultant, and by soliciting input from a technical expert panel (TEP). Following the identification of candidate risk adjustment variables, the measure developer developed risk models for the outcomes of severe obstetric complications and severe obstetric complications excluding blood transfusion-only encounters. The measure developer then utilized the variables included in the final risk models for use as the risk adjustment variables when calculating the risk

[715] eCQI Resource Center. (2022). Eligible Hospital/Critical Access Hospital Pre-rulemaking eCQMs. Available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

[716] The Joint Commission. (2021). eCQM Specifications 2022 Reporting Period. Available at: *https://www.jointcommission.org/-/media/tjc/documents/measurement/specification-manuals/2022-reporting-period/january-2022/ecqm_specifications_reportingperiod_2022.zip*.

[717] eCQI Resource Center. (2022). Eligible Hospital/Critical Access Hospital Pre-rulemaking eCQMs. Available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

standardized severe obstetric complication rates for the two versions of the measure outcome (with and without transfusion-only encounters).

Variables included in the measure's risk adjustment are: patient age; several preexisting conditions that are present on admission defined by ICD–10 codes (listed later in the section); pregnancy characteristics; laboratory tests and vital signs upon hospital arrival (hematocrit, white blood cell (WBC) count, heart rate, systolic blood pressure); long term anticoagulant medication use; and social risk measured by the presence of economic/housing instability.

The following preexisting conditions and pregnancy characteristics, defined by ICD–10 codes, are included in the measure's risk adjustment: Anemia, asthma, autoimmune disease, bariatric surgery, bleeding disorder, Body Mass Index (BMI), cardiac disease, gastrointestinal disease, gestational diabetes, Human Immunodeficiency Virus (HIV), Hypertension, mental health disorder, multiple pregnancy, neuromuscular disease, obstetric venous thromboembolism (VTE), other pre-eclampsia, placental accreta spectrum, placental abruption, placenta previa, preexisting diabetes, preterm birth, previous cesarean, pulmonary hypertension, renal disease, severe pre-eclampsia, substance abuse, and thyrotoxicosis.

(7) Measure Calculation

The measure is an outcome measure that assesses the risk-standardized proportion of eligible patients with severe obstetric complications, and the risk-standardized proportion of eligible patients with severe obstetric complications excluding transfusion-only hospital delivery encounters, which occur during the inpatient delivery hospitalization. The measure calculates the proportion of inpatient hospitalizations with severe obstetric complications occurring during the delivery hospitalization out of the total number of inpatient hospitalizations for patients delivering stillborn or live birth with greater than or equal to least 20 weeks and 0 days of gestation completed. The measure score will be reported as a rate per 10,000 deliveries.

(8) Data Submission and Reporting

We refer readers to: Section IX.E.10.e. of the preamble of this final rule for discussion of our previously finalized eCQM reporting and submission policies; and section IX.E.13.b. for the public reporting of eCQM data. Additionally, we refer readers to section IX.E.10.e.(4). where we discuss the use of the zero denominator declarations and case threshold exemption policies for hospitals.

We also refer readers to four related proposals discussed in the preamble of this final rule: (1) Section IX.E.10.e. where we discuss modifications to our reporting and submission requirements for eCQMs, including a discussion of our policy to require hospitals to report on the Severe Obstetric Complications eCQM; (2) section IX.E.5.c. for our policy to adopt the Cesarean Birth eCQM; (3) section IX.H.10.a.(2). of the preamble of this final rule for a discussion of similar policies to adopt these two perinatal eCQMs in the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs; and (4) section IX.E.8. where we are establishing a publicly-reported hospital designation to capture the quality and safety of maternity care and other related activities in advancing maternal health equity.

We invited public comment on this proposal.

Comment: Many commenters support the proposed adoption of the Severe Obstetric Complications eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. A few commenters indicated that they supported the measure because the measure aligns with existing state or Joint Commission reporting practices.

Response: We thank the commenters for their support and agree that the measure is in line with best practices for improving maternal morbidity and mortality rates.

Comment: A few commenters expressed support for the measure but had recommendations for how the measure should be implemented. A commenter recommended that COVID–19 patients not be excluded. A commenter recommended monitoring the measure in the future to determine whether modifications would be appropriate.

Response: We thank commenters for their recommendations. Regarding ongoing monitoring of the measure's performance, impact on reporters, and alignment with the measure's goals, we will monitor the data for any unintended consequences as part of the standard measure maintenance. Regarding the COVID–19 exclusions, at this time patients with confirmed diagnosis of COVID–19, with COVID–19-related respiratory condition or with COVID–19-related respiratory procedure are excluded from the measure calculation (87 FR 28514). The measure currently excludes COVID–19 patients from the measure cohort due to potential concerns of the COVID–19 impact on maternal health. We will continue to monitor the impact of COVID–19 on the measure's performance and alignment with the measure's goals as part of the standard measure maintenance.

Comment: A few commenters either expressed concern about the impact that public reporting may have on low volume hospitals or requested clarification on how non-birthing hospitals would be affected by the adoption of the measure.

Response: We thank the commenter for their requested clarification on how hospitals without birthing programs would be affected. In the FY 2023 IPPS/LTCH PPS proposed rule, we stated the Severe Obstetric Complications eCQM would be reported by all hospitals participating in the Hospital IQR Program except those hospitals that do not have an obstetrics department (87 FR 28512). We refer readers to section IX.E.10.e.(4). of this final rule where we discuss the Hospital IQR Program's zero denominator declarations and case threshold exemption policies for eCQMs. Zero denominator declarations allow a hospital whose EHR is capable of reporting eCQM data to submit a zero in the denominator for the reporting of an eCQM if the hospital does not have patients that meet the denominator criteria of that measure. Similarly, the case threshold exemptions policy allows for a hospital with five or fewer inpatient discharges per quarter or 20 or fewer inpatient discharges per year in a given denominator declaration be exempted from reporting on that individual eCQM. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387).

Comment: A commenter requested clarification on the definition and appropriate documentation of ''housing instability.''

Response: Housing instability is included in the risk adjustment for this measure due to evidence for its inclusion and availability in the EHR.[718]

[718] Centers for Medicare & Medicaid Services. (2021). Severe Obstetric Complications Electronic Clinical Quality Measure (eCQM) Methodology Report: Version 1. Available at: *https://*

Continued

While not explained in the proposed ruled, we are clarifying here that for purposes of this measure consistent with the measure specifications available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/*, economic housing instability is defined by the National Library of Medicine (NLM) value set [719] (2.16.840.1.113762.1.4.1029.292) comprising the following ICD–10 Z codes:

Z59.0	Homelessness
Z59.1	Inadequate housing
Z59.2	Discord with neighbors, lodgers and landlord
Z59.3	Problems related to living in residential institution
Z59.4	Lack of adequate food
Z59.5	Extreme poverty
Z59.6	Low income
Z59.7	Insufficient social insurance and welfare support
Z59.8	Other problems related to housing and economic circumstances
Z59.9	Problem related to housing and economic circumstances, unspecified

Comment: Several commenters did not support the measure because they believed it does not provide a meaningful measure for driving improvements in maternal health disparities and would not encourage hospitals to take the desired actions to mitigate severe maternal morbidity.

Response: We appreciate the commenters' concerns and respectfully disagree that the proposed measure does not provide a meaningful measure for driving improvements in maternal health disparities. We believe that this measure serves as a key activity in measuring and promoting quality improvement in maternity care by incentivizing hospitals to track and report severe obstetric complications and to publicly report measure data for transparency.

Comment: A commenter believed the measure may not be feasible.

Response: The measure developer's testing established the feasibility of the measure, first in 25 hospitals across eight healthcare sites and then in an additional hospital unaffiliated with the first 25, and across several different electronic health record systems. Based on the testing performed, we respectfully disagree that the measure is not feasible. All numerator indicators and 30 of 34 risk factors use easily mapped ICD–10 codes.[720] The two laboratory and two vital sign risk factors were chosen in part because of their availability and high rates of extractability from the medical record.

Comment: Several commenters either did not support the measure or expressed concerns about the proposed eCQM due to perceived resource limitations or because they believed the adoption timeline is too rapid.

Response: We acknowledge commenters' concerns and believe that the maternal health crisis requires urgent action without delay. In addition, we refer readers to section XII.B.4. for information on measure burden and note that, as with all Hospital IQR Program measures, we will monitor the data and any unintended consequences of the measure as part of the standard measure maintenance.

Comment: Many commenters recommended that the measure be adopted only once it is NQF endorsed. A few commenters recommended that the measure be risk adjusted or the exclusion criteria broadened. A few commenters recommended disaggregated or stratified data reporting. A commenter recommended that the measure be finalized with voluntary reporting and believed facilities are better positioned to set clinical priorities. A commenter recommended making the measure modifiable in case new risk factors are identified.

Response: We acknowledge commenters' recommendations that we seek NQF endorsement for the measure. As we stated in the FY 2023 IPPS/LTCH PPS proposed rule that the Severe Obstetric Complication eCQM was submitted to NQF in January 2022 and is currently under review (87 FR 28512). As there are currently no NQF-endorsed measures that address severe obstetric complications, we believe the exception at section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

We further thank commenters for their recommendations on changes to the measure specifications. We note that the measure is risk adjusted by several variables including patient age, several preexisting conditions, pregnancy characteristics, laboratory test results, long term anticoagulant medication use, and social risk (87 FR 28514). In the FY 2023 IPPS/LTCH PPS proposed rule, we also stated that the measure developer is currently conducting testing to determine approaches that would consider stratification based on sociodemographic factors (87 FR 28512). We also refer readers to section IX.B. (Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—Request for Information) for additional discussion on CMS' potential use of measure stratification in the future. We also regularly conduct measure maintenance and evaluate whether any modifications to measures are necessary. Any substantive changes to measures would be proposed in future notice-and-comment rulemaking.

In regard to voluntary reporting and prioritization, we believe that the maternal health crisis is urgent, maternal health inequities are unacceptable, and this persistent problem requires prompt action. Therefore, we believe allowing hospitals to self-select reporting beginning with the CY 2023 reporting period/FY 2025 payment determination and require

www.cms.gov/files/document/measure-methodology-report.pdf.

[719] *https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1029.292/expansion/Latest.*

[720] eCQI Resource Center. (2022). Eligible Hospital/Critical Access Hospital Pre-rulemaking eCQMs. Available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms.*

reporting beginning with the CY 2024 reporting period/FY 2026 payment determination is imperative.

Comment: A commenter recommended that the measure only report the second outcome of the Severe Obstetric Complications eCQM (the outcome of severe complications excluding transfusion-only encounters) because the commenter believes it would be inappropriate to publicly report the outcome of the severe obstetric complications with transfusion as the measure does not place a threshold on the number of units of blood involved in the transfusion. A commenter expressed concern that there may be negative unintended consequences.

Response: We appreciate commenters' concerns. As proposed, this measure is intended to report two outcomes: (1) Severe obstetric complications; and (2) severe obstetric complications but excluding delivery hospitalizations for which blood transfusion was the only numerator event (87 FR 28512, 28514). We believe that reporting on both outcomes is necessary to advance the goals of this eCQM. We note that we do not anticipate any unintended consequences, but as with all Hospital IQR Program measures, we will monitor the data for any unintended consequences as part of the standard measure maintenance.

Comment: A commenter expressed concern about the complexity of documenting the procedures and outcomes indicated in this measure and suggested that CMS assess whether the procedures reportable in the measures are documented in medical records (specifically, ventilation and transfusion).

Response: We thank the commenter for their recommendation. We appreciate the commenter's recommendation about evaluating the accuracy and applicability of the procedures reported under this measure. We note that these procedures are currently defined with ICD–10 procedure codes in the measure specifications, which can be found at *https://ecqi.healthit.gov/* (87 FR 28513 through 28514). The measure developer conducted medical record reviews to test the validity of the procedure codes and found high positive predictive value for both ventilation and transfusion.

Comment: A few commenters raised concerns that conditions accounted for in the numerator may not be predictable, preventable, or indicators of the quality of care provided. A commenter raised concerns that the eCQM data requirement is not aligned with current clinical practice guides on data collected, meaning that standards of practice will be negatively affected. A commenter raised concerns that the non-birthing hospitals may score disproportionately high if the measure is adopted because they may have zero-denominator measures. A few commenters requested clarification on how rates would be reportable if the volume of delivery hospitalizations was so low as to make only one rate reportable.

Response: We appreciate the commenters' concerns about measure data. As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, the measure developer conducted rigorous testing and found the measure to be valid, feasible, and reliable (87 FR 28513). With regard to concerns about low rates, we note that the measure developer conducted measure score reliability testing in both rural and urban settings, and that the thresholds for consideration for implementation of public reporting were found to be appropriate due to the risk-adjustment for the presence of economic/housing instability, the measure has a focus on accounting for potential disparities; the measure was tested in ten health systems with varying case volumes and no concerns were identified for low-volume hospitals (87 FR 28512). Regarding potential zero-denominator reporting hospitals, we believe this will not be a problem because, as stated previously, in the FY 2023 IPPS/LTCH PPS proposed rule that the Severe Obstetric Complications eCQM would be reported by all hospitals except those hospitals that do not have an obstetrics department and therefore zero-denominator hospitals would be exempt (87 FR 28512).

We refer readers to section IX.E.10.e.(4). of this final rule where we discuss the Hospital IQR Program's zero denominator declarations and case threshold exemption policies for eCQMs. Zero denominator declarations allow a hospital whose EHR is capable of reporting eCQM data to submit a zero in the denominator for the reporting of an eCQM if the hospital does not have patients that meet the denominator criteria of that hybrid measure (82 FR 38387). Similarly, the case threshold exemptions policy allows for a hospital with five or fewer inpatient discharges per quarter or 20 or fewer inpatient discharges per year in a given denominator declaration be exempted from reporting on that individual eCQM (82 FR 38387).

Comment: A commenter requested guidance on extrapolating data from clinical notes and patient records.

Response: We reiterate that this is an eCQM in which the data is collected through hospitals' EHR and designed to be calculated by the hospital's CEHRT (87 FR 28513). For more information regarding data submission, we refer readers to section IX.E.10.a. for discussion of our previously finalized eCQM reporting and submission requirements and to the measure specifications, which can be found at *https://ecqi.healthit.gov*.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

e. Hospital-Harm—Opioid-Related Adverse Events eCQM (NQF #3501e) Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

(1) Background

Opioids are among the most frequently implicated medications in adverse drug events among hospitalized patients.[721] The most serious opioid-related adverse events include those involving respiratory depression, which can lead to brain damage and death.[722] [723] [724] Opioid-related adverse events have both a negative impact on patients and financial implications. Patients who experience adverse events due to opioid administration have been noted to have 55 percent longer lengths of stay, 47 percent higher costs, 36 percent higher risk of 30-day readmission, and 3.4 times higher payments than patients without these adverse events.[725] While noting that data are limited, The Joint Commission suggested that opioid-induced respiratory arrest may contribute

[721] Davies EC, Green CF, Taylor S, Williamson PR, Mottram DR, et al. (2009) Adverse Drug Reactions in Hospital In-Patients: A Prospective Analysis of 3695 Patient-Episodes. PLoS ONE 4(2): e4439. doi:10.1371/journal.pone.0004439.

[722] Jungquist CR, Quinlan-Colwell A, Vallerand A, et al. (2020). American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Advancing Sedation and Respiratory Depression: Revisions. Pain Manag Nurs.21(1):7–25. Epub 2019 Jul 31.

[723] Ramachandran SK, Haider N, Saran KA, et al. (2011). Life-threatening critical respiratory events: a retrospective study of postoperative patients found unresponsive during analgesic therapy. Journal of Clinical Anesthesia. 23(3):207–213.

[724] Dahan A, Aarts L, Smith TW. (2010). Incidence, Reversal, and Prevention of Opioid-induced Respiratory Depression. *Anesthesiology.* 112(1):226–238.

[725] Kessler, E.R., Shah, M., Gruschkkus, S.K., et al. (2013). Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. Pharmacotherapy, 33(4): 383–91.

substantially to the 350,000 to 750,000 in-hospital cardiac arrests annually.[726]

Most opioid-related adverse events are preventable.[727] Of the opioid-related adverse drug events reported to The Joint Commission's Sentinel Event database, 47 percent were due to a wrong medication dose, 29 percent due to improper monitoring, and 11 percent due to other causes (for example, medication interactions and/or drug reactions).[728] In addition, in a review of cases from a malpractice claims database in which there was opioid-induced respiratory depression among post-operative surgical patients, 97 percent of these adverse events were judged preventable with better monitoring and response.[729]

While hospital quality interventions such as proper dosing, adequate monitoring, and attention to potential drug interactions that can lead to overdose are key to prevention of opioid-related adverse events, the use of these practices can vary substantially across hospitals.[730] [731] [732] In addition, administration of opioids also varies widely by hospital, ranging from 5 percent in the lowest-use hospital to 72 percent in the highest-use hospital.[733] Notably, hospitals that use opioids most frequently have increased adjusted risk of severe opioid-related adverse events.[734] The measure developer, under contract with CMS, developed the Hospital Harm–Opioid-Related Adverse Events eCQM to assess the rates of adverse events as well as the variation in rates among hospitals.

(2) Overview of Measure

The Hospital Harm—Opioid-Related Adverse Events eCQM is an outcome measure focusing specifically on opioid-related adverse events during an admission to an acute care hospital by assessing the administration of naloxone. Naloxone is a lifesaving emergent therapy with clear and unambiguous applications in the setting of opioid overdose.[735] [736] [737] [738] Naloxone administration has also been used in a number of studies as an indicator of opioid-related adverse events to indicate harm to a patient during inpatient admission to a hospital.[739] [740] The intent of this measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and to avoid harm, such as respiratory depression, which can lead to brain damage and death. This measure focuses specifically on in-hospital opioid-related adverse events, rather than opioid overdose events that happen in the community and may bring a patient into the ED.

The goal of this measure is to incentivize hospitals to closely monitor patients who receive opioids during their hospitalization to prevent serious adverse events. The measure requires evidence of hospital opioid administration prior to the naloxone administration during the first 24 hours after hospital arrival to ensure that the harm was hospital acquired and not due to an overdose that happened outside of the hospital.[741] This measure does not identify preventability of an individual harm instance or whether each instance of harm was an error, but rather, it assesses the overall rate of harm within a hospital by incorporating a definition of harm that is likely to be reduced as a result of hospital best practice.

The Hospital Harm—Opioid-Related Adverse Events eCQM was included as a measure undergoing field testing in the publicly available ''List of Measures Under Consideration for December 1, 2017'' (MUC List).[742] The measure was reviewed by the NQF MAP Hospital Workgroup in December 2017, and received the recommendation to refine and resubmit with completed test results demonstrating reliability and validity prior to rulemaking, as referenced in the ''2017–2018 Spreadsheet of Final Recommendations to HHS and CMS.'' [743]

This measure was submitted for endorsement consideration to NQF's Patient Safety Standing Committee for the Spring 2019 cycle. NQF reviewed the measure on June 21, 2019, but did not proceed with full endorsement consideration due to concerns with the performance gap criterion. In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19477), we proposed but did not finalize the adoption of the Hospital-Harm—Opioid-Related Adverse Events eCQM. Commenters provided measure suggestions and refinements, as outlined in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42459), and we decided to further assess the measure and the suggested considerations with intent to re-propose the measure. The main areas of suggestions were to better establish the connection between naloxone administration and an opioid-related event and consider narrowing the broad denominator that, as specified, may result in the calculation of very low rates of adverse events.

In response to the feedback received, the measure developer refined and retested the measure specifications. The measure developer limited the

[726] Overdyk, F.J. (2009). Postoperative Respiratory Depression and Opioids. Initiatives in Safe Patient Care. Available at: *https://www.initiatives-patientsafety.org/_files/ugd/ba15f5_d52da446e2f141d7be95d3a99b538a42.pdf.*

[727] Lee LA, Caplan RA, Stephens LS, et al. Postoperative opioid-induced respiratory depression: a closed claims analysis. Anesthesiology. 2015;122(3):659–665.

[728] The Joint Commission. (2012.) Safe Use of Opioids in Hospitals. The Joint Commission Sentinel Event Alert, 49:1–5. Available at: *https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/sea_49_opioids_8_2_12_finalpdf.pdf?db=web&hash=0135F306FCB10D919CF7572ECCC65C84.*

[729] Lee, L.A., Caplan, R.A., Stephens, L.S., et al. (2015). Postoperative opioid-induced respiratory depression: a closed claims analysis. Anesthesiology, 122(3): 659–65.

[730] Willens JS, Jungquist CR, Cohen A, Polomano R. (2013). ASPMN survey—nurses' practice patterns related to monitoring and preventing respiratory depression. Pain Management Nursing. 14(1):60–65.

[731] Meisenberg B, Ness J, Rao S, Rhule J, Ley C. (2017). Implementation of solutions to reduce opioid-induced oversedation and respiratory depression. Am J Health Syst Pharm. 74:162–169.

[732] Jungquist CR, Correll DJ, Fleisher LA, et al. (2016). Avoiding Adverse Events Secondary to Opioid-Induced Respiratory Depression: Implications for Nurse Executives and Patient Safety. Journal of Nursing Administration. 46(2):87–94.

[733] Herzig, S.J., Rothberg, M.B., Cheung, M., et al. (2014). Opioid utilization and opioid-related adverse events in nonsurgical patients in US hospitals. Journal of Hospital Medicine, 9(2): 73–81.

[734] *Ibid.*

[735] Surgeon General's Advisory on Naloxone and Opioid Overdose. (2018). Available at: *https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html.*

[736] Agency for Healthcare Research and Quality (AHRQ). (2017). Management of Suspected Opioid Overdose with Naloxone by Emergency Medical Services Personnel. Comparative Effectiveness Review No. 193. Available at: *https://effectivehealthcare.ahrq.gov/topics/emt-naloxon/systematic-review.*

[737] Substance Abuse and Mental Health Services Administration (SAMHSA). (2018). Opioid Overdose Prevention Toolkit: Information for Prescribers. Available at: *https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742.*

[738] Harm Reduction Coalition. (2020). Guide To Developing and Managing Overdose Prevention and Take-Home Naloxone Projects. Available at: *https://harmreduction.org/issues/overdose-prevention/developing-overdose-prevention-and-naloxone-projects/.*

[739] Eckstrand, J.A., Habib, A.S., Williamson, A., et al. (2009). Computerized surveillance of opioid-related adverse drug events in perioperative care: a cross-sectional study. Patient Safety Surgery, 3:18.

[740] Nwulu, U., Nirantharakumar, K., Odesanya, R., et al. (2013). Improvement in the detections of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools. European Journal of Clinical Pharmacology, 69(2): 255–59.

[741] #3501e Hospital Harm—Opioid-Related Adverse Events, Apr 02, 2021. Measure Information Form. *https://nqfappservices storage.blob.core.windows.net/proddocs/27/Spring/2021/measures/3501e/shared/3501e.zip.*

[742] National Quality Forum. (2017). List of Measures Under Consideration for December 1, 2017. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[743] National Quality Forum. 2017–2018 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

denominator to encounters where patients received at least one opioid during the hospitalization. The measure developer constrained the numerator to those patients with an opioid administration that preceded the subsequent naloxone administration by no more than a 12-hour time window, to ensure that a hospital administered opioid was the cause for the naloxone administration. The measure developer also updated the value sets to ensure that the most current codes for hospital administered opioids and naloxone are used and that the codes harmonize across other current eCQMs in our quality reporting programs. Finally, the measure was re-tested by the measure developer for feasibility at 23 hospital test sites using four different EHR vendor systems and for the scientific acceptability of the measure's properties including reliability and validity at six beta implementation test sites.[744] Participant test sites varied by EHR vendor systems, bed size, geographic location, teaching/non-teaching status, and urban/rural representation.

The Hospital Harm—Opioid-Related Adverse Events eCQM (NQF #3501e) was then re-submitted to the NQF for the Spring 2021 review cycle and received NQF endorsement on December 7, 2021.[745] The MAP Rural Health Advisory Group also reviewed the MUC List and Hospital Harm—Opioid-Related Adverse Events eCQM (MUC2021–084) on December 8, 2021 and voted majority support in agreement on the applicability of the eCQM to rural health settings.[746] The refined and retested eCQM was also re-considered by the MAP Hospital Workgroup on December 15, 2021, which voted to support the measure for rulemaking.[747] The MAP Coordinating Committee, which provides direction to the MAP workgroups, then reviewed the measure on January 19, 2022 [748] and upheld the MAP Hospital Workgroup recommendation to support the measure for rulemaking.[749]

We believe this measure will provide hospitals with reliable and timely measurement of their opioid-related adverse event rates, which is a high-priority measurement area. We believe implementation of this measure can lead to safer patient care by incentivizing hospitals to implement or refine clinical workflows that facilitate evidence-based use and monitoring when administering opioids. We also believe implementation of this measure may result in fewer patients experiencing adverse events associated with the administration of opioids, such as respiratory depression, which can lead to brain damage and death. This measure addresses the quality priority of ''Making Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Healthcare Harm.''[750]

For detailed information on the Hospital Harm—Opioid-Related Adverse Events eCQM, we refer readers to the measure specifications, available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

(3) Data Sources

The eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data and then submitted by hospitals to CMS.

As with all quality measures we develop, testing was performed to confirm the feasibility of the measure, data elements, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Testing demonstrated no missing or erroneous data (0 percent) for all six implementation test sites. These results suggest that all critical data elements are reliably and consistently captured in patient EHRs, and that measure implementation is feasible. Testing also showed that the positive predictive value (PPV),[751] which describes the probability that a patient with a positive result (numerator case) identified by the EHR data was also a positive result verified by review of the patient's medical record done by a clinical adjudicator, was high at all hospital testing sites (98 percent in one hospital to 100 percent in the five other hospitals). Testing was completed using output from the Measure Authoring Tool (MAT) in 23 hospitals using four different EHR systems for feasibility and six different hospitals for implementation testing for reliability and validity.

(4) Outcome

This measure assesses the proportion of inpatient hospital encounters where patients 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (naloxone) within 12 hours. This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting.

(5) Cohort

This measure's cohort includes all patients ages 18 years and older at the start of the encounter, and for whom at least one opioid medication was administered during the encounter. An inpatient hospitalization includes time spent in the ED or in observation status when the patients are ultimately admitted to inpatient status.

(6) Inclusion and Exclusion Criteria

This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting. There are no denominator exclusions.

(7) Risk Adjustment

This measure is not risk adjusted for chronic opioid use, as most instances of opioid-related adverse events should be preventable for all patients regardless of prior exposure to opioids or chronic opioid use.

Generally, patient characteristics, including gender, age, race/ethnicity, reasons for hospitalization, clinical status when patients arrive at the hospital, or comorbidities can influence the risk of harm occurring during a hospitalization.[752] Therefore, if hospitals care for patients with different

[744] National Quality Forum. #3501e Hospital Harm—Opioid-Related Adverse Events. Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3501e*.

[745] National Quality Forum. (2021). Hospital Harm—Opioid Related Adverse Events. Available at: *https://www.qualityforum.org/QPS/3501e*.

[746] National Quality Forum. (2022). Measure Applications Partnership Rural Health Advisory Group Virtual Review Meeting Summary, December 8, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96571*.

[747] Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary. December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629*.

[748] Measure Applications Partnership Coordinating Committee 2021–2022 Review Web Meeting: Meeting Summary. January 19, 2022. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96709*.

[749] Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care Final Report. March 3, 2022. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

[750] More information on CMS' Meaningful Measures Framework is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html*.

[751] ''Predictive Value.'' Farlex Partner Medical Dictionary. Available at: *https://medical-dictionary.thefreedictionary.com/predictive+value*.

[752] National Quality Forum. Glossary of Terms. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=73681*.

degrees of risk, then it may be important to account for such case mix to compare hospital performance.[753] However, opioid-related adverse events should be avoidable regardless of patient risk, particularly when the opioid was given after patients have arrived at the hospital.[754] During measure development, in evaluating whether this measure needed to be risk adjusted, the measure developer considered the following in determining whether risk adjustment is warranted for this measure: Patients are at risk of the harm regardless of their demographic and clinical characteristics; most incidents of harm are linkable to care provision under the hospital control, for example, harms caused by excessive or inappropriate medication dosing; and there is evidence that the risk of harm can be largely reduced by following best care practices independent of patient inherent risks. For example, patients with multiple risk factors can still avoid the harm event when providers adhere to care guidelines.

Opioid-related adverse events should be avoidable regardless of patient risk, particularly when the opioid was given after patients have arrived at the hospital.[755] While certain patients may require higher doses to achieve pain control or are more sensitive to opioids (depending on their age, sex, and weight), the most common cause is hospital administration of excessive doses and inadequate monitoring.[756] Because the dosing of opioids and the intensity of patient monitoring is entirely under the control of providers in hospitals, the risk of an opioid-related adverse event can be reduced by following best practices.[757] [758] [759] Therefore, the measure developer did not think risk adjustment is warranted for this measure.

To provide supportive evidence of the clinical rationale for not risk adjusting, the measure developer examined the measure performance rate in various subgroups of population. All these analyses demonstrated no pattern in measure performance rates across subgroups.[760] During measure development, TEP members gave feedback on whether the measure required risk adjustment and agreed with this rationale. Subsequently the NQF Scientific Methods Panel (SMP), the Patient Safety Standing Committee, and the Consensus Standards Advisory Committee (CSAC) also agreed with this approach.[761] [762] [763]

(8) Measure Calculation

The Hospital Harm—Opioid-Related Adverse Events eCQM is an outcome measure that defines the indication of a harm for an opioid-related adverse event by assessing administration of an opioid antagonist (naloxone). The numerator is the number of inpatient hospitalizations where an opioid antagonist (naloxone) was administered outside of the operating room and within 12 hours following administration of an opioid medication. Only one numerator event is counted per encounter. The denominator includes inpatient hospitalizations for patients 18 years or older during which at least one opioid medication was administered. An inpatient hospitalization includes time spent in the ED or in observation status when the patients are ultimately admitted to inpatient status.

To calculate the hospital-level measure result, divide the total numerator events by the total number of qualifying inpatient encounters (denominator). Qualifying inpatient encounters include all patients 18 years of age or older at the start of the encounter with at least one opioid medication administered during the encounter. The measure does not include naloxone use in the operating room where it could be part of the sedation plan as administered by an anesthesiologist or nurse anesthetist. Uses of naloxone for procedures outside of the operating room (such as bone marrow biopsy) are counted in the numerator as its use will indicate the patient was over sedated.[764] The measure numerator identifies a harm using the administration of naloxone, and purposely does not include any medications that combine naloxone with other agents.

(9) Data Submission and Reporting

We proposed the adoption of the Hospital-Harm—Opioid-Related Adverse Events eCQM as part of the Hospital IQR Program for which hospitals can self-select beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to section IX.E.10.e. of the preamble of this final rule for a discussion of our previously finalized eCQM reporting and submission policies, as well as our proposal to modify these eCQM reporting and submission requirements. Additionally, we refer readers to section IX.H.10.a.(2). of the preamble of this final rule for a discussion of a similar proposal to adopt this measure in the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs.

We invited public comment on this proposal.

Comment: Many commenters supported adoption of the Hospital Harm—Opioid-Related Adverse Events eCQM (NQF #3501e) beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. Several commenters believed that measure implementation will result in fewer adverse events associated with the administration of opioids (for example, respiratory depression) and will lead to safer patient care and saved lives. A few commenters agreed that the measure

[753] National Quality Forum. Developing and Testing Risk Adjustment Models for Social and Functional Status-Related Risk Within Healthcare Performance Measurement: Final Technical Guidance—Version 4. August 30, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96087*.

[754] The Joint Commission. (2012). Safe Use of Opioids in Hospitals. The Joint Commission Sentinel Event Alert, 49:1–5. Available at: *https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/sea_49_opioids_8_2_12_finalpdf.pdf?db=web&hash=0135F306FCB10D919CF7572ECCC65C84*.

[755] *Ibid.*

[756] Dahan A, Aarts L, Smith TW. Incidence, Reversal, and Prevention of Opioid-induced Respiratory Depression. Anesthesiology. 2010;112(1):226–238.

[757] Practice Guidelines for the Prevention, Detection, and Management of Respiratory Depression Associated with Neuraxial Opioid Administration: An Updated Report by the American Society of Anesthesiologists Task Force on Neuraxial Opioids and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. 2016 Mar;124(3):535–52.

[758] Jungquist CR, Quinlan-Colwell A, Vallerand A, et al. American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Advancing Sedation and Respiratory Depression: Revisions. Pain Manag Nurs. 2020 Feb;21(1):7–25. Epub 2019 Jul 31.

[759] Dahan A, Aarts L, Smith TW. Incidence, Reversal, and Prevention of Opioid-induced Respiratory Depression. Anesthesiology. 2010;112(1):226–238.

[760] #3501e Hospital Harm—Opioid-Related Adverse Events, Apr 02, 2021. Measure Information Form. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/27/Spring/2021/measures/3501e/shared/3501e.zip*.

[761] National Quality Forum. Scientific Methods Panel Measure Evaluation Web Meeting—Spring 2021 Meeting Summary. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95246*.

[762] National Quality Forum. Patient Safety Spring 2021 Cycle. Memo: Consensus Standards Approval Committee (CSAC). November 30, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96423*.

[763] National Quality Forum. Consensus Standards Approval Committee (CSAC) Voting Results and Decisions for Spring 2021 Measures. November 30, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96528*.

[764] Nwulu, U., Nirantharakumar, K., Odesanya, R., McDowell, S.E., & Coleman, J.J. Improvement in the detection of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools. Eur J Clin Pharmacol. 2013;69(2), 255–259.

will incentivize hospitals to implement or refine clinical workflows and implement continual monitoring protocols when administering opioids. Several commenters recognized and appreciated the refinements made to the measure since its earlier proposal in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19477). A few commenters applauded CMS for expanding the choices of available eCQMs for reporting in the Hospital IQR Program.

A few commenters highlighted the potential positive impact measure reporting may have on vulnerable populations. A commenter noted that opioid use is a serious concern in rural health and appreciated the transparency this measure will bring. Another commenter noted this measure will help to track and improve quality for older adult patients and a commenter stated that the measure will help to address the disproportionate overdose deaths occurring among racial and ethnic minorities.

Response: We thank commenters for their support and input on the inclusion of the measure. We agree that this measure captures important quality information that is critical to patient safety and improving patient outcomes.

Comment: A few commenters did not support the inclusion of the measure due to concerns that implementation could lead to unintended consequences for care delivery, as the potential for lower performance could lead to hesitancy in hospitals' or clinicians' use of naloxone in clinically appropriate, rapid-response situations. These commenters also noted that implementation could lead to undertreatment of pain after surgery. A commenter recommended that a more robust methodology be developed for identifying the cause of the event as opioid-related. Another commenter suggested we consider ways to distinguish appropriate use of naloxone in the measure specifications.

Response: We thank commenters for their input and feedback on this measure. We acknowledge that some stakeholders have expressed concern that implementation of the measure could result in deterring or delaying clinically appropriate administration of naloxone or under-prescribing of opioids for pain control when clinically necessary. We reiterate that naloxone is a life-saving emergent therapy with clear and unambiguous applications in the setting of opioid overdose,[765] [766] [767] [768] and we outline below the methodology deployed to ascertain that numerator cases flagged by the measure are true positives.

During testing at six sites, the measure developer examined whether numerator cases identified by the measure were true positives and found that in 98 percent of cases naloxone was administered for respiratory depression or reduced arousal or for opioid reversal and resulted in improvement in the patient's level of consciousness.[769] To examine if the numerator cases identified by the quality reporting engine are true positives, clinical abstractors pulled additional information regarding the indication for and subsequent reaction to the naloxone administration from the nurse notes and physician orders. We also found that some, but not all, test sites also used the Pasero Opioid-induced Sedation Scale (POSS) [770] in recording the appropriateness of opioid dosage, which is a 5 point scale as follows:

- S = Sleep, easy to arouse; acceptable; no action necessary; may increase opioid dose if needed.
- 1 = Awake and alert: acceptable; no action necessary; may increase opioid dose if needed.
- 2 = Slightly drowsy, easily aroused; acceptable; no action necessary; may increase opioid dose if needed.
- 3 = Frequently drowsy, arousable, drifts off to sleep during conversation; unacceptable; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory; decrease opioid dose 25 percent to 50 percent or notify prescriber or anesthesiologist for orders; consider administering a non-sedating, opioid-sparing nonopioid, such as acetaminophen or a NSAID, if not contraindicated.
- 4 = Somnolent, minimal or no response to verbal and physical stimulation; unacceptable; stop opioid; consider administering naloxone; notify prescriber or anesthesiologist; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory.

The POSS is a valid, reliable tool used to assess sedation when administering opioid medications to manage pain. The POSS is endorsed by The Joint Commission and the American Society for Pain Management Nursing to help prevent adverse opioid-related respiratory events.[771] Of the identified numerator cases where POSS were used, most showed an initial POSS of 3 or 4. After the naloxone administration, patients' POSS decreased to 1 or 2. We also note that patients showing no immediate responses may be due to the inadequate dosage of naloxone, as there were some instances identified during the manual abstraction where patients became responsive only after the second naloxone. Overall, the developer found that the use of naloxone in the absence of opioid toxicity was rare.[772] We are confident that hospitals and clinicians will continue to administer naloxone when it is clinically necessary and will monitor for evidence of unintended consequences as we do for all Hospital IQR Program measures.

Comment: A few commenters raised concerns about implementation burden. Two commenters highlighted that there is a substantial cost and time burden faced by hospitals when adopting new eCQMs. A commenter also reported they are already collecting a similar opioid measure.

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[765] Surgeon General's Advisory on Naloxone and Opioid Overdose. Available at: *https://www.surgeongeneral.gov/priorities/opioidoverdose-prevention/naloxone-advisory.html.*

[766] Agency for Healthcare Research and Quality (AHRQ). (2017). Management of Suspected Opioid Overdose with Naloxone by Emergency Medical Services Personnel. Comparative Effectiveness Review No. 193. Available at: *https://effectivehealthcare.ahrq.gov/topics/emt-naloxon/systematic-review.*

[767] Substance Abuse and Mental Health Services Administration (SAMHSA). (2018). Opioid Overdose Prevention Toolkit: Information for Prescribers. Available at: *https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742.*

[768] Harm Reduction Coalition. (2020). Guide To Developing and Managing Overdose Prevention and Take-Home Naloxone Projects. Available at: *https://harmreduction.org/issues/overdose-prevention/developing-overdose-prevention-and-naloxone-projects/.*

[769] #3501e Hospital Harm—Opioid-Related Adverse Events, Apr 02, 2021. Testing Attachment. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/27/Spring/2021/measures/3501e/shared/3501e.zip.*

[770] Davis, C., Geik, C., Arthur, K., Fuller, J., Johnston, E., Levitt, F., Leung, E., McCart, G., McMichael, D., Painter, J., Staublin, T., & Walroth, T. (2017). A Multisite Retrospective Study Evaluating the Implementation of the Pasero Opioid-Induced Sedation Scale (POSS) and Its Effect on Patient Safety Outcomes. Pain management nursing: official journal of the American Society of Pain Management Nurses, 18(4), 193–201. *https://doi.org/10.1016/j.pmn.2017.03.006.*

[771] Davis, C., Geik, C., Arthur, K., Fuller, J., Johnston, E., Levitt, F., Leung, E., McCart, G., McMichael, D., Painter, J., Staublin, T., & Walroth, T. (2017). A Multisite Retrospective Study Evaluating the Implementation of the Pasero Opioid-Induced Sedation Scale (POSS) and Its Effect on Patient Safety Outcomes. *Pain management nursing: official journal of the American Society of Pain Management Nurses, 18*(4), 193–201. *https://doi.org/10.1016/j.pmn.2017.03.006.*

[772] #3501e Hospital Harm—Opioid-Related Adverse Events, Apr 02, 2021. Testing Attachment. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/27/Spring/2021/measures/3501e/shared/3501e.zip.*

Response: We thank commenters for their feedback. We highlight that this measure is one of the available (not required) eCQMs hospitals may self-select for submission beginning with the CY 2024 reporting period. The addition of this eCQM further advances CMS' goal of transitioning to a fully digital quality measures landscape, promoting interoperability that will help decrease burden.

We also recognize there is an opioid measure in the Hospital IQR Program, Safe Use of Opioids—Concurrent Prescribing (NQF #3316e) (84 FR 42598). While both measures are designed to reduce adverse events or harms associated with opioid use, the main focus of each measure is different. The Safe Use of Opioids—Concurrent Prescribing eCQM focuses on concurrent prescriptions of opioids and benzodiazepines at discharge, an area of high-risk prescribing (84 FR 42598). The Hospital Harm—Opioid-Related Adverse Events eCQM is designed to reduce adverse events associated with the administration of opioids in the hospital setting by assessing the administration of naloxone as an indicator of harm (87 FR 28516). We believe implementation of the Hospital Harm—Opioid-Related Adverse Events eCQM can lead to safer patient care by incentivizing hospitals to track and improve their monitoring of patients who receive opioids during hospitalization.

Comment: A few commenters offered recommendations to augment the measure's exclusions; for example, by excluding patients who receive naloxone for indications other than over-sedation (for example, pruritis).

Response: We thank commenters for their input and recommendations regarding potential measure exclusions. We note the exclusions as presented in the measure specifications in the proposed rule (87 FR 28516) were evaluated and endorsed by the NQF Scientific Methods Panel (SMP),[773] the Patient Safety Standing Committee,[774] and the Consensus Standards Advisory Committee (CSAC).[775] This eCQM was also evaluated by the MAP Hospital Workgroup and the MAP Coordinating Committee,[776] [777] [778] who both supported the measure for rulemaking. We aim to be as inclusive as possible in defining a measure cohort to ensure the measure will have the most impact on important subgroups of patients. We will take these suggestions into consideration and are assessing the feasibility of capturing the indication(s) for administration of naloxone.

Comment: Two commenters requested clarifications on the measure. A commenter requested if CMS has target data for hospitals to compare their own results to and whether zero events is an attainable target. Another commenter requested more information about which opioids would be included in the calculations of ''opioid-related adverse events'' and if the measure is based on prescription history within a provider's electronic health record.

Response: We thank commenters for their questions. Regarding the commenter's question on benchmarks, we note that the Hospital IQR Program does not implement benchmarks or target levels of performance for its measures as it is a pay-for-reporting quality program. Moreover, the intent of this measure is not to reduce clinically appropriate use of naloxone, nor to bring the measure rate to zero, but to identify if hospitals have particularly high rates of naloxone use as an indicator of high rates of over-administration of opioids in the inpatient setting, and thereby incentivize improved clinical practices when administering opioids (87 FR 28516).

Regarding which opioids are included in the calculation of opioid-related adverse events, the opioid value set includes all formulations of opioids that may be administered in an inpatient or outpatient setting regardless of intended use (87 FR 28516). It also includes combination medications that contain both an opioid and another class of medication, as it is possible to overdose on these combination medications (87 FR 28516).

Comment: A few commenters were generally supportive of the measure but questioned whether the adoption will be impactful (especially given the resources and time needed for hospitals to implement the measure) as they noted the overall number of inpatient naloxone rescue events is small. A commenter did not support measure adoption noting it focused on rare events in the inpatient setting rather than targeting the primary drivers of the opioid epidemic. A commenter recommended additional testing in a broader range of hospitals and vendor systems to further assess variation in performance scores. A few commenters requested we collect and analyze several years of data before adding this measure to a pay-for-performance program.

Response: We acknowledge that some stakeholders have expressed concern regarding the measure's impact given the small number of overall events. However, our overall analysis during testing demonstrated the rate of ORAE ranged from 1.1 to 6.1 per 1,000 qualified inpatient encounters, signaling there is still opportunity for improvement. As noted in the proposed rule, we tested feasibility at 23 hospital test sites using four different EHR vendor systems and for the scientific acceptability of the measure's properties including reliability and validity at six beta implementation test sites (87 FR 28516). Participant test sites varied by EHR vendor systems, bed size, geographic location, teaching/non-teaching status, and urban/rural representation. This far exceeds NQF measure evaluation criteria for testing eCQMs, which requires testing using at least two EHR vendor systems (87 FR 28516). We will monitor the performance gap as hospitals begin to report this measure. Future potential use of the measure for a pay-for-performance program would be through notice-and-comment rulemaking.

Comment: A few commenters supported inclusion of the measure into the Hospital IQR Program but requested changes to the reporting schedule and requirements. A commenter stated the measure should not impact hospital payment until the CY 2025 reporting period/FY 2027 payment determination, while another commenter suggested mandating opioid-related adverse event reporting by all hospitals in the program.

Response: We thank commenters for their support and input. This measure

[773] National Quality Forum. Scientific Methods Panel Measure Evaluation Web Meeting—Spring 2021 Meeting Summary. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95246.* 1096.

[774] National Quality Forum. Patient Safety Spring 2021 Cycle. Memo: Consensus Standards Approval Committee (CSAC). November 30, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96423.* 1097.

[775] National Quality Forum. Consensus Standards Approval Committee (CSAC) Voting Results and Decisions for Spring 2021 Measures. November 30, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96528.*

[776] Measure Applications Partnership Hospital Workgroup Web Review Meeting: Meeting Summary. December 15, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96629.*

[777] Measure Applications Partnership Coordinating Committee 2021–2022 Review Web Meeting: Meeting Summary. January 19, 2022. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96709.*

[778] Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care Final Report. March 3, 2022. Available at: *https://www.qualityforum.org/Projects/i-/MAP/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report.aspx#onclick=%E2%80%9D_gaq.push.%E2%80%98_trackEvent%E2%80%99,%E2%80%99Download%E2%80%99,%E2%80%99PDF%E2%80%99,this.href;%E2%80%9D.*

was proposed for inclusion as one of the eCQMs hospitals can self-select for reporting beginning with the CY 2024 reporting period/FY 2026 payment determination, which we believe allows sufficient time for hospitals to prepare and implement the measure. The addition of this eCQM further advances CMS' goal of transitioning to a fully digital quality measures landscape, and we will take the commenter's suggestion to make this eCQM mandatory under consideration for future rulemaking.

Comment: A few commenters requested we monitor clinical literature and hospital administration practices in the coming years to determine if the measurement area remains of critical importance.

Response: We thank the commenters for their feedback. We will continue to evaluate and refine the measure through implementation as necessary.

Comment: A commenter suggested considering the potential value of risk adjustment for the measure.

Response: We thank the commenter for their feedback to consider risk adjusting this measure. We did not apply risk adjustment in the measure, given strong evidence that most instances of severe over-sedation requiring naloxone for reversal can be avoided by following best practices; and given that opioid dosing and patient monitoring are under the control of providers in hospitals, such that risk can be minimized by following best practices.[779] [780]

We will continue to evaluate and refine the measure through implementation as necessary.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

f. Global Malnutrition Composite Score eCQM (NQF #3592e) Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

(1) Background

From 1960 until the start of the COVID–19 pandemic,[781] life expectancy for the total population in the U.S. increased by almost 10 years.[782] While adults are living longer lives, the amount of time spent in poor health at the end of life is similarly increasing.[783] Studies found that healthy nutrition is indeed more important for healthy aging than generally recognized.[784] Malnutrition includes undernutrition (wasting, stunting, underweight), inadequate vitamins or minerals, overweight, and obesity, and can result in diet-related noncommunicable diseases.[785] The developmental, economic, social, and medical impacts of the global burden of malnutrition are serious and lasting, for individuals and their families, for communities, and for countries.[786] Malnutrition is complex and may be both associated with and exacerbated by chronic conditions, age-related cognitive or physical changes, medication side effects, and poverty.[787] Evidence shows that healthy eating contributes to prevention and risk reduction of many common chronic health conditions prevalent in older adults including hypertension, heart disease, heart failure, diabetes, obesity, certain cancers, and osteoporosis.[788] While it is estimated that sixty percent of older adults manage two or more chronic health conditions, many underuse preventive services, including those related to nutrition.[789] Research indicates that preventive screening and interventions may reduce risk of malnutrition in older adults and improve quality of life, particularly for individuals with chronic conditions.[790] While disease-related malnutrition is not limited to older adults, it is more frequent among those with higher age, and the consequences appear to be more severe in older persons due to their impaired regenerative capacity, inflammation, and other factors.[791] Malnutrition remains a challenge for older adults in the U.S. as approximately 7.7 percent of seniors, or 5.5 million, are food insecure annually with reports of reduced quality, variety, or desirability of diet while 3.1 percent, or 2.1 million are very low food insecure with reports of multiple indications of disrupted eating patterns and reduced food intake.[792] [793] From late September through mid-October 2021, U.S. Census Bureau data indicates that more than 2.5 million adults ages 65 and older responded ''sometimes'' or ''often'' when questioned about the frequency of not having enough food to eat in the past seven days.[794] As our population continues to age, it is expected that 1 in 5 residents will be 65 years or older by the year 2030 [795] and malnutrition risk among seniors is likely to increase.[796]

One factor contributing to the burden of malnutrition is health disparity across racial and ethnic groups. Black, Hispanic, and other non-White older adult populations have higher hunger

[779] Practice Guidelines for the Prevention, Detection, and Management of Respiratory Depression Associated with Neuraxial Opioid Administration: An Updated Report by the American Society of Anesthesiologists Task Force on Neuraxial Opioids and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. 2016 Mar;124(3):535–52.

[780] Lee LA, Caplan RA, Stephens LS, et al. Postoperative opioid-induced respiratory depression: a closed claims analysis. Anesthesiology. 2015;122(3):659–665.

[781] Islam N, Jdanov D A, Shkolnikov V M, Khunti K, Kawachi I, White M et al. (2021). Effects of covid-19 pandemic on life expectancy and premature mortality in 2020: time series analysis in 37 countries. BMJ 375:e066768 doi:10.1136/bmj-2021–066768.

[782] United States Census Bureau. (2020). Living Longer: Historical and Projected Life Expectancy in the United States, 1960 to 2060. Available at: *https://www.census.gov/content/dam/Census/library/publications/2020/demo/p25-1145.pdf*.

[783] Roberts SB, Silver RE, Das SK, Fielding RA, Gilhooly CH, Jacques PF, et al. (2021) Healthy Aging-Nutrition Matters: Start Early and Screen Often. Adv Nutr. 12(4):1438–1448. doi: 10.1093/advances/nmab032.

[784] *Ibid.*

[785] World Health Organization. (2021). Malnutrition. Available at: *https://www.who.int/news-room/fact-sheets/detail/malnutrition*.

[786] World Health Organization. (2021). Malnutrition. Available at: *https://www.who.int/news-room/fact-sheets/detail/malnutrition*.

[787] Barker CA, Gout BS, et al. (2011). Hospital malnutrition prevalence, identification, and impact on patients and the healthcare system. International Journal of Environmental Research and Public Health.8:514–527.

[788] Wright NC, Looker AC, Saag KG, et al. (2014). The recent prevalence of osteoporosis and low bone mass in the United States based on bone mineral density at the femoral neck or lumbar spine. J Bone Miner Res. 29(11):2520–2526. *http://onlinelibrary.wiley.com/doi/10.1002/jbmr.2269/epdf*.

[789] US Department of Health and Human Services. (2020). Office of Disease Prevention and Health Promotion. Older Adults: Overview. Healthy People 2020 website. Available at: *https://www.healthypeople.gov/2020/topics-objectives/topic/older-adults*.

[790] Mangels, AR. (2018). Malnutrition in Older Adults. American Journal of Nursing. 118(3):34–41. doi: 10.1097/01.NAJ.0000530915.26091.be.

[791] Norman K, Haß U, Pirlich M. (2021). Malnutrition in Older Adults—Recent Advances and Remaining Challenges. Nutrients. 13, 2764. Available at: *https://doi.org/10.3390/nu13082764*.

[792] Feeding America. (2019). The State of Senior Hunger in America in 2017: An Annual Report. Available at: *https://www.feedingamerica.org/sites/default/files/2019-05/state-of-senior-hunger-2017_full-report.pdf*.

[793] United States Department of Agriculture Economic Research Service. (2021). Definitions of Food Security. Available at: *https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/definitions-of-food-security.aspx*.

[794] United States Census Bureau. (2021). Week 39 Household Pulse Survey: September 29—October 11. Available at: *https://www.census.gov/data/tables/2021/demo/hhp/hhp39.html*.

[795] United States Census Bureau. (2018). Older People Projected to Outnumber Children for First Time in U.S. History. Available at: *https://www.census.gov/newsroom/press-releases/2018/cb18-41-population-projections.html*.

[796] Haines J, LeVan D, Roth-Kauffman MM. (2020). Malnutrition in the Elderly: Underrecognized and Increasing in Prevalence. Clinical Advisor. Available at: *https://www.clinicaladvisor.com/home/topics/geriatrics-information-center/malnutrition-in-the-elderly-underrecognized-and-increasing-in-prevalence/*.

rates than White populations.[797] Black Americans and Hispanic Americans are nearly 2.5 times and 1.4 times as likely as White Americans, respectively, to lack access to a full-service grocery store; this contributes to higher rates of food insecurity and can increase risk of malnutrition.[798] Black, Hispanic, and other non-White Americans are also at higher risk for many chronic diseases, emphasizing the importance of addressing nutrition through both prevention and management of these condition—especially when they cannot access healthy food.[799]

Patients over 65 comprise more than one-third of all discharges and nearly 13 million seniors are hospitalized each year.[800] [801] While federal data indicate that approximately 8 percent of all hospitalized adults have a diagnosis of malnutrition,[802] [803] additional research finds that malnutrition and malnutrition risk can be found in 20 to 50 percent of hospitalized adults.[804] [805] This indicates that between 910,000 and 6.5 million hospitalized seniors may experience malnutrition.[806] Hospitalized adults with a diagnosis of malnutrition have a longer length of stay, higher costs, more comorbidities, five times the likelihood of death, and greater risk of infectious disease and injury compared with other adult inpatients without malnutrition.[807] [808] Malnutrition may also contribute to post-hospital syndrome—described as ''an acquired, transient period of vulnerability'' following hospitalization[809]—which may dramatically increase the risk of readmission.[810] [811]

Partly due to the substantial impacts on clinical outcomes,[812] malnutrition imposes a serious burden on the healthcare system.[813] Hospitalized patients with poor nutrition have been estimated to incur approximately 300 percent higher healthcare costs than those who are adequately nourished.[814] Reports indicate that the average cost for an individual hospital stay (including both direct and indirect costs) for a malnourished patient is $25,600 while it is only $13,900 for a well-nourished patient; [815] further, malnutrition-associated diseases among older adults in the US has been estimated to cost $51.3 billion annually.[816]

Hospitals have an opportunity to identify malnutrition during the patient admission process and to address it efficiently and effectively with individualized interventions that could optimize outcomes including reduced readmissions and lengths of stay.[817] Research demonstrates that there is significant room to improve identification, diagnosis, and treatment of malnutrition in hospitalized patients.[818] [819] Nutrition screening is the first step in optimal malnutrition care and triggers a nutrition assessment for patients found to be at risk.[820] [821]

We have consistently received stakeholder input requesting the addition of nutrition measures to the Hospital IQR Program measure set to address malnutrition of hospitalized patients, including comments described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51639), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53535), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50056), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49561). In the FY 2018 IPPS/LTCH PPS proposed rule, we solicited public comments on potential future inclusion of malnutrition eCQMs in the Hospital IQR Program (82 FR 20060 through 20061), and in the FY 2018 IPPS/LTCH PPS final rule we provided a summary of these comments (82 FR 38379 through 38380). Commenters expressed support and stated that Medicare beneficiaries would benefit from the adoption of malnutrition eCQMs that support prompt malnutrition screening, assessment, diagnosis, and development of a care plan (82 FR 38379). In addition, the commenters stated that eCQMs specifically designed and tested to be used with patient data documented directly in the EHR would likely impose minimal data collection

[797] United States Department of the Treasury CDFI Fund Capacity Building Initiative. (2012). A Summary of Searching for Markets: The Geography of Inequitable Access to Healthy & Affordable Food in the United States. Available at: *https://www.reinvestment.com/wp-content/uploads/2015/12/Searching_For_Markets-Summary_2011.pdf*.

[798] Ibid.

[799] Dawson MD, Blancato B. (2021). To Advance Health Equity, Measure Hospital Malnutrition Care. Health Affairs. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20210930.667648/full/*.

[800] Gorman A. (2016). Elderly Hospital Patients Arrive Sick, Often Leave Disabled. Kaiser Health Network. Available at: *https://khn.org/news/elderly-hospital-patients-arrive-sick-often-leave-disabled/*.

[801] Mattison M. (2021). Hospital Management of Older Adults. Available at: *https://www.uptodate.com/contents/hospital-management-of-older-adults*.

[802] United States Agency for Healthcare Research and Quality. (2016). Non-maternal and non-neonatal inpatient stays in the United States involving malnutrition, 2016. Available at: *https://hcup-us.ahrq.gov/reports/ataglance/HCUPMalnutritionHospReport_083018.pdf*.

[803] Valladares AF, McCauley SM, Khan M, D'Andrea C, Kilgore K, Mitchell K. (2021). Development and Evaluation of a Global Malnutrition Composite Score. Journal of the Academy of Nutrition and Dietetics. doi: *https://doi.org/10.1016/j.jand.2021.02.002*.

[804] Pereira GF., Bulik CM, Weaver MA, Holland WC, Platts-Mills TF. (2015). Malnutrition among cognitively intact, noncritically ill older adults in the emergency department. Ann Emerg Med. 65: 85–91.

[805] Barker CA, Gout BS, et al. (2011). Hospital malnutrition prevalence, identification, and impact on patients and the healthcare system. International Journal of Environmental Research and Public Health. 8:514–527.

[806] United States Government Accountability Office. (2019). Report to Congressional Requestors. Nutrition Assistance Programs: Agencies Could Do More to Help Address the Nutritional Needs of Older Adults. Available at: *https://www.gao.gov/assets/gao-20-18.pdf*.

[807] United States Agency for Healthcare Research and Quality. (2016). Healthcare Cost and Utilization Project: Non-maternal and Non-Neonatal Inpatient Stays in the United States Involving Malnutrition 2016. Available at: *https://hcup-us.ahrq.gov/reports/ataglance/HCUPMalnutritionHospReport_083018.pdf*.

[808] United States Agency for Healthcare Research and Quality. (2013). Characteristics of Hospital Stays Involving Malnutrition, 2013. HCUP Statistical Brief #210. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb210-Malnutrition-Hospital-Stays-2013.jsp*.

[809] Krumholz, HM. (2013). Post-hospital syndrome—an acquired, transient condition of generalized risk. New England Journal of Medicine. 368(2):100–2.

[810] Sauer, A, Luo M. (2015) Role of Malnutrition in Increasing Risk of Hospital Readmissions. Abbott Nutrition Health Institute. Available at: *http://static.abbottnutrition.com/cms-prod/anhi.org/img/Role-Of-Malnutrition-In-Increasing-Risk-OfHospital-Readmissions-article.pdf*.

[811] Guenter P, Jensen G, Patel V, Miller S, Mogensen KM, Malone A, et al. (2015). Addressing disease-related malnutrition in hospitalized patients: a call for a national goal. Joint Commission Journal on Quality and Patient Safety.41(10):469–73.

[812] Norman K., Pichard C., Lochs H., Pirlich M. (2008). Prognostic impact of disease-related malnutrition. Clin. Nutr. 27, 5–15.

[813] Khalatbari-Soltani S., Marques-Vida, P. (2015). The economic cost of hospital malnutrition in Europe; a narrative review. Clin. Nutr. ESPEN. 10, e89–e94.

[814] Correia M.I., Waitzberg D.L. (2003). The impact of malnutrition on morbidity, mortality, length of hospital stay and costs evaluated through a multivariate model analysis. Clin Nutr. 22(3):235–9.

[815] *Ibid.*

[816] Snider J.T., Linthicum M.T., Wu Y., et al. (2014). Economic burden of community-based disease-associated malnutrition in the United States. JPEN. 38(2 Suppl):77s–85s.

[817] *Ibid.*

[818] Kabashneh S., Alkassis S., Shanah L., Ali H.. (2020). A Complete Guide to Identify and Manage Malnutrition in Hospitalized Patients. Cureus. doi: 10.7759/cureus.8486.

[819] Fitall E., Jones Pratt K., McCauley S.M., Astrauskas G., Heck T., Hernandez B., et al. (2019). Improving Malnutrition in Hospitalized Older Adults: The Development, Optimization, and Use of a Supportive Toolkit. Journal of the Academy of Nutrition and Dietetics. 119(9):S25–S31 Available at: *https://www.sciencedirect.com/science/article/pii/S2212267219305039*.

[820] Skipper A. (2008). Nutrition care process and model part I: the 2008 update. J Am Diet Assoc.108(7):1113–7.

[821] Swan W., Vivanti A., Hakel-Smith N.A., Trostler N., Beck Howarter N., Papoutsakis C. (2017). Nutrition Care Process and Model Update: Toward Realizing People-Centered Care and Outcomes Management. Journal of the Academy of Nutrition and Dietetics. 117(12):2003–2014.

and reporting burden (82 FR 38379 through 38380). The commenters further stated that the inclusion of malnutrition eCQMs in the Hospital IQR Program measure set could help improve outcomes and quality of life for patients, especially for seniors and the disadvantaged (82 FR 38380). We believe adopting a malnutrition measure will address several priority areas identified in the CMS Equity Plan for Medicare, including evaluating impacts of disparities, integrating equity solutions across CMS programs, and increasing the ability of the healthcare workforce to meet the needs of [822] [823]

Therefore, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28518 through 28523) rule, we proposed to adopt the Global Malnutrition Composite Score eCQM (NQF #3592e) beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. At this time, CMS quality reporting programs do not include quality measures that specifically address malnutrition. In the CY 2022 Physician Fee Schedule (PFS) final rule (86 FR 65970 through 65971), we adopted the Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols Improvement Activity (IA) as part of the Merit-based Incentives Payment System (MIPS), which incentivizes MIPS-eligible clinicians to create or improve, and then implement, protocols for identifying and providing appropriate support to: a) Patients with or at risk for food insecurity, and b) patients with or at risk for poor nutritional status.[824] In conjunction with adopting the IA under MIPS, we believe adoption of the Global Malnutrition Composite Score eCQM in the Hospital IQR Program has the potential to improve care delivery in the inpatient setting and is likely to ameliorate food insecurity and malnutrition and lead to better health outcomes.

Under the CMS Meaningful Measures Framework,[825] the Global Malnutrition Composite Score eCQM addresses the quality priority of ''Promote Effective Communication & Coordination of Care'' as well as ''Promote Effective Prevention and Treatment of Chronic Disease.'' Under the CMS Meaningful Measures 2.0 Initiative, the Global Malnutrition Composite Score eCQM addresses the quality priority of ''Affordability and Efficiency.'' [826]

(2) Overview of Measure

The Global Malnutrition Composite Score eCQM assesses adults 65 years of age and older admitted to inpatient hospital service who received care appropriate to their level of malnutrition risk and malnutrition diagnosis, if properly identified. Best practices for malnutrition care recommend inpatients be screened for malnutrition risk, assessed to confirm findings of malnutrition if found at-risk, and have the proper severity of malnutrition indicated in their diagnosis along with a corresponding nutrition care plan that addresses the respective severity of malnutrition.[827] [828]

The malnutrition composite measure includes four component measures, which are first scored separately, and then integrated into an overall composite score. The overall composite score is derived from averaging the individual performance scores of the following four component measures:

- Screening for malnutrition risk at admission;
- Completing a nutrition assessment for patients who screened for risk of malnutrition;
- Appropriate documentation of malnutrition diagnosis in the patient's medical record if indicated by the assessment findings; and
- Development of a nutrition care plan for malnourished patients including the recommended treatment plan.

Together, the four component measures represent the key processes of care of malnutrition associated with the risk identification, diagnosis, and treatment of malnutrition in older hospitalized adults as supported by clinical guidelines and submitted evidence.[829]

The four component measures were initially submitted for endorsement as individual process measures in the NQF 2015–2017 Health and Well-Being Project.[830] The NQF declined to endorse any of the individual component measures based on evidence, provider burden concern (including timing of malnutrition screening and assessment), and the unavailability of necessary data elements to report the eCQMs.[831] The 2015–2017 Health and Well-Being Standing Committee recommended combining individual measures or all measures into a composite measure to make the measure more meaningful by including both the screening and the development of a nutrition care plan into one measure.[832]

Based on these recommendations, the measure developer conducted additional testing. The four component measures were piloted as a single composite measure at a large hospital in the Midwest and the testing results demonstrated that the measures were usable for identifying key improvement areas in malnutrition care related to identifying risk, assessing for malnutrition, developing the appropriate care plan, and ensuring the diagnosis of malnutrition was documented to support follow-up care.[833] Subsequently, a group of 27 hospitals adopted and reported on the use of the four component measures to guide various projects focused on improving care provided to hospitalized patients who were malnourished or at risk of malnutrition.[834] The

[823] Centers for Medicare & Medicaid Services. CMS Equity Plan for Medicare. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/equity-plan.*

[824] Centers for Medicare & Medicaid Services. Quality Payment Program. Improvement Activities Performance Category: Traditional MIPS Requirements. Available at: *https://qpp.cms.gov/mips/improvement-activities.*

[825] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[826] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[827] Nepple K.G., Tobert C.M., Valladares A.F., Mitchell K., Yadrick M. (2019). Enhancing Identification and Management of Hospitalized Patients Who Are Malnourished: A Pilot Evaluation of Electronic Quality Improvement Measures. Journal of the Academy of Nutrition and Dietetics. 119(9):S32–S39.

[828] McCauley S.M., Barrocas A., Malone A. (2019). Hospital Nutrition Care Betters Patient Clinical Outcomes and Reduces Costs: The Malnutrition Quality Improvement Initiative Story. Journal of the Academy of Nutrition and Dietetics. 119(9):S11–S14.

[829] Valladares A.F., McCauley S.M., Khan M., D'Andrea C., Kilgore K., Mitchell K. (2021). Development and Evaluation of a Global Malnutrition Composite Score. Journal of the Academy of Nutrition and Dietetics. 122(2):P251–P253.

[830] National Quality Forum. Health and Well-Being Project 2015–2017. Available at: *https://www.qualityforum.org/ProjectDescription.aspx?projectID=80741.*

[831] National Quality Forum. Prevention and Population Health, Fall 2020 Cycle: CDP Report. Available at: *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=86178.*

[832] National Quality Forum. Health and Well-Being 2015–2017 Final Report. Available at: *https://www.qualityforum.org/Publications/2017/04/Health_and_Well-Being_2015-2017_Final_Report.aspx.*

[833] Nepple K.G., Tobert C.M., Valladares A.F., Mitchell K., Yadrick M. (2019). Enhancing identification and management of hospitalized patients who are malnourished: a pilot evaluation of electronic quality improvement measures. Journal of the Academy of Nutrition and Dietetics. 119: S32–S39.

[834] Valladares A.F., Kilgore K.M., Partridge J., Sulo S., Kerr K.W., McCauley S. (2021). How a malnutrition quality improvement initiative furthers malnutrition measurement and care: results

Continued

participating hospitals reported changes in measure performance based on implementation of cyclical quality improvement initiatives at their respective institutions. Multivariate analyses were then conducted to identify the relationships between performance on the four component measures with patient outcomes of 30-day readmission and length of stay. The study results concluded that the four component measures could be implemented in a cohort of diverse hospitals and lead to meaningful improvements in measure performance as all four components of the composite measure were significantly associated with improved outcomes for 30-day readmissions.[835] [836] Prior analyses also reported early nutrition interventions were associated with reduced patient length of stay.[837] [838] [839] [840] [841] Following measure testing, the measure developer returned to NQF with the composite eCQM for consideration in the Fall 2020 measure cycle.

The Global Malnutrition Composite Score eCQM (MUC20–0032) was included in the publicly available ''List of Measures Under Consideration for December 21, 2020'' (MUC List).[842] The measure was voted on and approved by the Scientific Methods Panel in October 2020.[843] The MAP Rural Health Advisory Group reviewed the measure during its January 2021 meeting and agreed that this measure was suitable for use with rural providers in the Hospital IQR Program.[844] The MAP subsequently offered conditional support for rulemaking, pending NQF endorsement of the measure.[845]

The composite measure was initially reviewed by the NQF Prevention and Population Health (PPH) Standing Committee for endorsement suitability during its February 2021 measure evaluation meeting [846] and the full review of the measure was detailed in the NQF Prevention and Population Health Fall 2020 Consensus Development Process (CDP) Report.[847] The NQF PPH Standing Committee members agreed malnutrition is a significant contributor to infections and pressure ulcers requiring treatment, especially for patients transferred to other care facilities (such as an inpatient rehabilitation hospital), and held a robust discussion with most members supporting the presented evidence and topic area importance that assigns accountability to the hospital team.[848] Some PPH Standing Committee members questioned the lack of validated and standardized screening and assessment tools specified in the first two components. The measure developer along with the measure steward stated that objective, validated screening tools [849] and standardized assessment tools [850] can be implemented to capture variables from structured EHR data fields, such as BMI, dietary history, recent weight loss, illness severity, laboratory values, and age. After further discussion on performance gaps and the ability to discern differences within and between populations, many PPH Standing Committee members stated they wanted to review additional performance data for the eCQM.[851] The measure developer submitted the requested performance data for the PPH NQF Standing Committee to review, discuss, and revote at the NQF Standing Committee post-comment meeting on June 3, 2021.[852] At that time, the NQF PPH Standing Committee voted on the overall suitability for endorsement and the NQF Consensus Standards Approval Committee (CSAC) subsequently endorsed the measure (NQF #3592e).[853]

The measure specifications for the Global Malnutrition Composite Score eCQM can be found on the eCQI Resource Center website, available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

(3) Data Sources

The eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data and then submitted by hospitals to CMS.

(4) Measure Calculation

The Global Malnutrition Composite Score eCQM consists of four component measures, which are first scored separately.[854] [855] The overall composite

from a hospital learning collaborative. JPEN J Parenter Enteral Nutr. 45: 366–371.

[835] *Ibid.*

[836] Anghel S., Kerr K.W., Valladares A.F., Kilgore K.M., Sulo S. (2021). Identifying patients with malnutrition and improving use of nutrition interventions: A quality study in four US hospitals. Nutrition. 91–92; 111360.

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[838] Meehan A., Loose C., Bell J., Partridge J., Nelson J., Goates S. (2017). Health system quality improvement: impact of prompt nutrition care on patient outcomes and health care costs. J Nurs Care Qual. 2016; 31(3): 217–223.

[839] Sriram K., Sulo S., VanDerBosch G., et al. A comprehensive nutrition-focused Quality Improvement Program reduces 30-day readmissions and length of stay in hospitalized patients. JPEN J Parenter Enteral Nutr. 41(3): 384–391.

[840] Somanchi M., Tao X., Mullin G.E. (2011). The facilitated early enteral and dietary management effectiveness trial in hospitalized patients with malnutrition. JPEN J Parenter Enteral Nutr. 35(2): 209–216.

[841] Deutz N.E., Matheson E.M., Matarese L.E., et al. (2016). Readmission and mortality in malnourished, older, hospitalized adults treated with a specialized oral nutritional supplement: A randomized clinical trial. Clin Nutr. 35(1): 18–26.

[842] Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 21, 2020. Available at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf*.

[843] National Quality Forum. MAP 2020–2021 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Available at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

[844] National Quality Forum. Measure Applications Partnership Rural Health Workgroup Virtual Review Meeting Summary. January 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94656*.

[845] National Quality Forum. MAP 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. March 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94894*.

[846] National Quality Forum. Measure Evaluation Web Meeting #1: Prevention and Population Health. February 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94816*.

[847] National Quality Forum. Prevention and Population Health Fall 2020 CDP Report. October 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96457*.

[848] National Quality Forum. Measure Worksheet—3592—Fall 2020 Cycle. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95961*.

[849] Skipper A., Coltman A., Tomesko J., Piemonte T.A., Handu D., Cheng F.W., et al. Position of the Academy of Nutrition and Dietetics: Malnutrition (Undernutrition) Screening Tools for All Adults. Journal of the Academy of Nutrition and Dietetics. 120(4):709–713.

[850] White J.V., Guenter P., Jensen G., Malone A., Schofield M. Consensus Statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: Characteristics Recommended for the Identification and Documentation of Adult Malnutrition (Undernutrition). J Am Diet Assoc;112(5):730–738.

[851] National Quality Forum. Post-Comment Web Meeting (Fall 2020 Cycle) Comments Received. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95422*.

[852] National Quality Forum. Post-Comment Web Meeting (Fall 2020 Cycle) Memo. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95421*.

[853] National Quality Forum. Consensus Standards Approval Committee Prevention and Population Health Fall 2020 Review. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95602*.

[854] Valladares A.F., McCauley S.M., Khan M., D'Andrea C., Kilgore K., Mitchell K. (2021). Development and Evaluation of a Global Malnutrition Composite Score. Journal of the Academy of Nutrition and Dietetics. Available at:

score is derived from averaging the individual performance scores of the four component measures. The malnutrition component measures are all fully specified for use in EHRs. Table IX.E–04. outlines the data specification(s) and data sources for each of the four components.

TABLE IX.E-04. GLOBAL MALNUTRITION COMPOSITE SCORE ECQM COMPONENTS AND DATA SOURCES

Component	Description	Data Sources
Completion of a Malnutrition Screening	Patients age 65 years and older who were screened for malnutrition	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Malnutrition Screening - Completed Malnutrition Screening Time Stamp
Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition	Patients age 65 years and older identified as at-risk for malnutrition based on a malnutrition screening who have a nutrition assessment documented in the medical record	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Malnutrition Screening - Malnutrition Screening Result - Completed Nutrition Assessment - Completed Nutrition Assessment Time Stamp
Appropriate Documentation of a Malnutrition Diagnosis	Patients age 65 years and older and found to be malnourished based on a completed nutrition assessment who have documentation of a malnutrition diagnosis	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Nutrition Assessment - Nutrition Assessment Result - Malnutrition Diagnosis
Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment	Patients age 65 years and older and found to be malnourished based on a completed nutrition assessment who have a documented nutrition care plan in the medical record.	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Nutrition Assessment - Nutrition Assessment Result - Documented Nutrition Care Plan

(5) Measure Numerator

The Global Malnutrition Composite Score eCQM numerator is comprised of the four component measures, that are individually scored for patients 65 years of age and older who are admitted to an acute inpatient hospital. Details on the numerator for each component are specified in Table IX.E–05.

TABLE IX.E-05. GLOBAL MALNUTRITION COMPOSITE SCORE ECQM COMPONENTS' NUMERATOR DESCRIPTIONS

Component	Numerator
Completion of a Malnutrition Screening	Patients in the denominator who have a malnutrition screening documented in the medical record
Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition	Patients in the denominator who have a nutrition assessment documented in the medical record
Appropriate Documentation of a Malnutrition Diagnosis	Patients in the denominator with a diagnosis of malnutrition documented in the medical record
Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment	Patients in the denominator who have a nutrition care plan documented in the medical record

(6) Measure Denominator

The measure denominator is the composite, or total, of the four component measures for patients aged 65 years and older who are admitted to an acute inpatient hospital. Details on the denominator (and any exclusions) for each component are specified in Table IX.E–06.

https://www.jandonline.org/article/S2212-2672(21)00075-7/fulltext.

[855] National Quality Forum. #3592e Global Malnutrition Composite Score. Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3592e.*

TABLE IX.E-06. GLOBAL MALNUTRITION COMPOSITE SCORE ECQM COMPONENTS' DENOMINATOR DESCRIPTIONS AND EXCLUSIONS

Component	Denominator	Denominator Exclusions
Completion of a Malnutrition Screening	Patients age 65 years and older at time of admission who are admitted to an inpatient hospital	Patients with a length of stay of less than 24 hours
Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition	Patients age 65 years and older at time of admission who are admitted to an inpatient hospital and were identified as at-risk for malnutrition upon completing a malnutrition screening	Patients with a length of stay of less than 24 hours
Appropriate Documentation of a Malnutrition Diagnosis	Patients age 65 years and older at time of admission who are admitted to an inpatient hospital with findings of malnutrition upon completing a nutrition assessment	Patients with a length of stay of less than 24 hours
Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment	Patients age 65 years and older at time of admission who are admitted to an inpatient hospital with findings of malnutrition upon completing a nutrition assessment.	Patients with a length of stay of less than 24 hours

Each measure component is a proportion with a possible performance score of 0 to 100 percent. After each component score is calculated individually, an unweighted average of all four scores is completed to determine the final composite score with a total score ranging from 0 to 100 percent.[856]

(7) Data Submission and Reporting

We are proposed the adoption of the Global Malnutrition Composite Score eCQM as part of the Hospital IQR Program measure set for which hospitals can self-select beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to section IX.E.10.e. of this final rule for our previously finalized eCQM reporting and submission requirements, as well as proposed modifications for these requirements. We also refer readers to section IX.H.10.a.(2). of the preamble of this final rule for discussion of a similar proposal to adopt this measure in the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs.

We invited public comment on this proposal.

Comment: Many commenters supported our proposal to adopt the Global Malnutrition Composite Score eCQM beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. Many commenters supported our proposal to adopt this measure, expressing their beliefs that the measure will provide valuable information and insights to providers, patients, families, communities, as well as policymakers. Many commenters supported this measure because of its positive implications for healthcare, including improving care coordination and the quality of life after hospitalization, providing timely interventions and connections to community resources, and reducing issues like costly outcomes, readmissions, lengths of stay, complications, and mortality. Many commenters appreciated that this measure may help close the gap between identification of and intervention for malnutrition. Several commenters indicated appreciation that this measure may help raise awareness and support for screening for malnutrition by clinicians, helping to ensure that hospitals are consistently screening patients. Many commenters supported our proposal because they believe that malnutrition is a significant issue for aging populations and is tied to health outcomes. Several commenters appreciated that this measure is a step toward improving and standardizing care for malnutritioned older adults. Several commenters appreciated our proposal, noting that it will fill a measurement gap because malnutrition is otherwise unaddressed by our other quality reporting and value-based purchasing programs. A few commenters suggested that we should focus on whether patients received appropriate nutrition while in the hospital, or whether their nutritional needs were met after discharge. A commenter noted that operationalizing this measure may be more challenging for rural hospitals without full-time dietician support. A commenter suggested we consider trying to assess upstream flagging measures for nutrition prior to hospitalization.

Response: We thank the commenters for their support of our proposal to adopt the Global Malnutrition Composite Score eCQM. The developmental, economic, social, and medical impacts of the global burden of malnutrition are serious and lasting, for individuals and their families, for communities, and for countries (87 FR 28518). We agree that this measure may provide valuable information and may help us begin to address the serious burden that malnutrition imposes on the healthcare system. We agree that disease-related malnutrition, while not limited to older adults, is more frequent among those with higher age, and the consequences appear to be more severe in older persons (87 FR 28518). This measure will capture important information that may be critical to improving care for aging people with malnutrition. Further, we believe that adoption of the Global Malnutrition Composite Score eCQM has the potential to improve care delivery in the inpatient setting and is likely to ameliorate food insecurity and malnutrition and lead to better health outcomes by delivering necessary attention and resources to hospitalized individuals with nutrition needs that can improve their quality of care. With regard to dietician support, while we acknowledge that hospitals have different staffing levels, we believe that nutrition screening is an important aspect of a patient's holistic health and it is the responsibility of all clinicians to support appropriate nutrition, particularly in inpatient settings where hospitalized individuals can receive

[856] Valladares A.F., McCauley S.M., Khan M., D'Andrea C., Kilgore K., and Mitchell K. (2021). Development and Evaluation of a Global Malnutrition Composite Score. Journal of the Academy of Nutrition and Dietetics. 122(2): p251–253.

resources, education, and appropriate nutrition to address their needs.

Comment: Many commenters supported our proposal because it aligns with our health equity priorities for reducing disparities in healthcare. Many commenters supported our proposal because they believe that malnutrition disproportionately affects vulnerable populations and anticipate this measure may be important to advancing health equity. Several commenters appreciated that the measure will help provide a safety net for vulnerable patients and historically underserved populations. A few commenters noted that malnutrition disproportionately impacts rural residents and emphasized that this measure may be particularly helpful for rural communities.

Response: We thank the commenters for their support. We agree that adopting a malnutrition measure may help address several priority areas identified in the CMS Framework for Health Equity,[857] including evaluating impacts of disparities, integrating equity solutions across CMS programs, and increasing the ability of the healthcare workforce to meet the needs of underserved populations (87 FR 28520). We also note that addressing nutrition disparities is a priority for the Biden-Harris administration, which has set a goal of ending hunger and increasing healthy eating so fewer Americans experience diet-related diseases.[858] We agree that health disparities are one factor that contributes to the burden of malnutrition across racial and ethnic groups and inpatient hospitals have an opportunity to identify malnutrition and optimize outcomes for patients including reduced readmissions, which are significantly higher for Black and Hispanic Americans as well as American Indian and Alaskan Natives.[859] [860] This measure may help underscore the importance of addressing nutrition for the health of vulnerable patients in historically underserved populations (87 FR 28519). We also note that the MAP Rural Health Advisory Group reviewed this measure and determined it would be suitable for use with rural providers in the Hospital IQR Program (87 FR 28521).

Comment: A commenter requested that we provide a direction score to help hospitals better understand their performance.

Response: We appreciate the commenter's suggestion and will consider it as part of our educational materials and outreach during implementation of this measure. We note that the Hospital IQR Program does not implement benchmarks or target levels of performance for its measures as it is a pay-for-reporting program. However, a higher score on the Global Malnutrition Composite Score eCQM represents better quality of care.

Comment: A commenter recommended that we refine the exclusion criteria to give more time for sufficient nutrition assessments.

Response: We thank the commenter for their feedback. We note that the NQF assessed and endorsed this measure with the current exclusion criteria.[861] We will continue to evaluate the appropriateness of refinements to the exclusion criteria upon implementation of the measure.

Comment: A commenter expressed concern that the measure could be overly subjective and noted that providers do not control patient choices regarding the management of their own health.

Response: We acknowledge the commenter's concern that providers do not control patient choices; however, we respectfully disagree that the measure is overly subjective. The four component measures that make up this composite eCQM represent the key processes of care of malnutrition associated with the risk and identification, diagnosis, and treatment of malnutrition in older hospitalized adults as supported by clinical guidelines and submitted evidence (87 FR 28520). Measure testing across a group of 27 hospitals found that the four component measures could be implemented in a cohort of diverse hospitals and lead to meaningful improvements in measure performance as all four components of the composite measure were significantly associated with improved outcomes for 30-day readmissions (87 FR 28521). Based on the measure testing and ultimate NQF endorsement of this measure, we believe that adoption of the Global Malnutrition Composite Score eCQM has the potential to improve the quality of care delivery in the inpatient setting and is likely to ameliorate food insecurity and malnutrition and lead to better health outcomes, particularly in inpatient settings where hospitalized individuals can receive resources, education, and appropriate nutrition to address their needs.

Comment: A few commenters expressed concern that this measure may be duplicative of the food insecurity attestation proposed in the Screening for Social Drivers of Health measure. A commenter did not support our proposal to adopt this measure for that same concern.

Response: We acknowledge the commenters' concern, however we believe that the measures, while related, are not duplicative. The Screening for Social Drivers of Health measure, discussed in section IX.E.5.b.(1). of the preamble of this final rule, and the Global Malnutrition Composite Score eCQM both speak to nutrition as a driver of health because it is an important contributor to a healthful population. However, the measures address different but related goals. The Screening for Social Drivers of Health measure focuses on incentivizing the screening and identifying of patients for food insecurity, defined as limited or uncertain access to adequate quality and quantity of food (87 FR 28500), while the Global Malnutrition Composite Score eCQM focuses not only on screening for malnutrition risk (of which food insecurity may be a contributing factor), but also the performance of a nutrition assessment and development of a care plan for identified malnourished patients (87 FR 28520). We believe these two measures are equally important and complementary, but not duplicative as they measure different aspects of quality care processes.

Comment: Several commenters addressed requiring reporting of this measure. A few commenters suggested we require reporting on this eCQM. A few commenters specifically supported the measure as a measure that hospitals can choose to self-select. A few commenters expressed their belief that this measure may not be relatively important for the Hospital IQR Program and recommended that we not require reporting of it in the future. A commenter suggested that we not

[857] Centers for Medicare & Medicaid Services. CMS Framework for Health Equity. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity*.

[858] The White House. White House Announces Conference on Hunger, Nutrition, and Health in September. May 4, 2022. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/04/white-house-announces-conference-on-hunger-nutrition-and-health-in-september/*.

[859] Rodriguez-Gutierrez R., Herrin J., Lipska K.J. Racial and Ethnic Differences in 30-Day Hospital Readmissions Among US Adults With Diabetes. (2019). JAMA Network Open. 2019;2(10):e1913249. Available at: *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2752820*.

[860] Centers for Medicare & Medicaid Services Office of Minority Health. Medicare Hospital Readmissions Among Minority Populations. (2015). Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Dwnld-MedicareHospitalReadmissionsAmongMinorityPopulations.pdf*.

[861] National Quality Forum. Consensus Standards Approval Committee Prevention and Population Health Fall 2020 Review. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95602*.

require reporting of this measure until after several years' worth of the measure data have been validated.

Response: We appreciate the commenters' feedback on our proposal to adopt, but not yet require, reporting on this eCQM. We believe that our proposal is balanced so as to provide hospitals with the option of reporting on this new eCQM. The addition of this eCQM further advances CMS' goal of transitioning to a fully digital quality measures landscape, and we will take the commenters' suggestion to make this eCQM mandatory under consideration as we begin to collect data. We note that any proposal to require reporting this eCQM would be made through future notice-and-comment rulemaking.

Comment: Several commenters expressed concern about implementing and operationalizing this measure given the detailed and complex nature of the measure specification and because of competing EHR-related proposals and reporting requirements. They believe that implementation would require updates to EHRs and workflows. A commenter requested additional implementation guidance to support standardized implementation across hospitals.

Response: We appreciate the commenters' concerns about implementation of the measure and note that the measure uses data collected through hospital's EHRs and is designed to be calculated by the hospital's CEHRT, thereby reducing reporting burden and complexity. Regarding resource commitments and the proposed adoption schedule, we believe that the design of the measure is balanced to provide hospitals sufficient information for driving healthful outcomes by quickly identifying and addressing patients' nutrition needs and additional resource allocations to support reporting for this eCQM, particularly in the hospital inpatient older adult population of which up to 6.5 million patients experience malnutrition (87 FR 28519). We also remind hospitals that they may self-select to report on this eCQM; it is not a required eCQM for the CY 2024 reporting period/FY 2026 performance period. As we noted in the FY 2023 IPPS/LTCH PPS proposed rule, the measure developer conducted testing on this measure across a group of 27 hospitals and concluded that the four component measures could be implemented in a cohort of diverse hospitals and lead to meaningful improvements in measure performance (87 FR 28521). For implementation guidance, we refer readers to the measure specifications, implementation guide, and other resources, which can be found on the eCQI Resource Center website, available at: *https://ecqi.healthit.gov*.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

g. Hospital-Level, Risk Standardized Patient-Reported Outcomes Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #3559), Beginning With Two Voluntary Reporting Periods in CYs 2025 and 2026, Followed by Mandatory Reporting for Eligible Elective Procedures Occurring July 1, 2025 Through June 30, 2026, Impacting the FY 2028 Payment Determination and for Subsequent Years

(1) Background

Approximately six million adults aged 65 or older suffer from osteoarthritis in the U.S.[862] Osteoarthritis accounts for more than half of all arthritis-related hospitalizations,[863] and in 2013 there were approximately 1,023,000 hospitalizations for osteoarthritis.[864] Hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,[865] and roughly 80 percent of patients with osteoarthritis have some limitation in mobility.[866] Elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans.[867] THA and TKA offer significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without resulting in a high risk of complications or death.[868] [869] [870] [871] However, not all patients experience benefit from these procedures.[872] Many patients note that their pre-operative expectations for functional improvement have not been met.[873] [874] [875] [876] In addition, clinical practice variation has been well documented in the U.S.,[877] [878] [879] readmission and complication rates vary across hospitals,[880] [881] and international

[862] Arthritis Foundation. Arthritis By the Numbers Book of Trusted Facts and Figures. 2018: *https://www.arthritis.org/getmedia/e1256607-fa87-4593-aa8a-8db4f291072a/2019-abtn-final-march-2019.pdf*. Accessed March 8, 2019.

[863] Levit K., Stranges E., Ryan K., Elixhauser A. HCUP Facts and Figures, 2006: Statistics on Hospital-based Care in the United States. 2008. *Available at: http://www.hcup-us.ahrq.gov/reports.jsp*.

[864] Torio C.M., B.J., National inpatient hospital costs: the most expensive conditions by payer, 2013. HCUP statistical brief #204. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. Rockville, MD, Agency for Healthcare Research and Quality. *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb204-Most-Expensive-Hospital-Conditions.pdf*. Accessed February 2021.

[865] Guccione A.A., Felson D.T., Anderson J.J., et al. The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. American journal of public health. 1994;84(3):351–358.

[866] Michaud C.M., McKenna M.T., Begg S., et al. The burden of disease and injury in the United States 1996. Population health metrics. 2006;4:11. doi: 10.1186/1478–7954–4–11.

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[868] Rissanen P., Aro S., Slatis P., Sintonen H., Paavolainen P. Health and quality of life before and after hip or knee arthroplasty. The Journal of arthroplasty. 1995;10(2):169–175.

[869] Wiklund I., Romanus B. A comparison of quality of life before and after arthroplasty in patients who had arthrosis of the hip joint. The Journal of bone and joint surgery. American volume. 1991;73(5):765–769.

[870] Laupacis A., Bourne R., Rorabeck C., et al. The effect of elective total hip replacement on health-related quality of life. The Journal of bone and joint surgery. American volume. 1993;75(11):1619–1626.

[871] Ritter M.A., Albohm M.J., Keating E.M., Faris P.M., Meding J.B. Comparative outcomes of total joint arthroplasty. The Journal of arthroplasty. 1995;10(6):737–741.

[872] National Joint Registry. National Joint Registry for England and Wales 9th Annual Report 2012. Available at: *https://www.hqip.org.uk/wp-content/uploads/2018/02/national-joint-registry-9th-annual-report-2012.pdf*.

[873] Suda A.J., Seeger J.B., Bitsch R.G., Krueger M., Clarius M. Are patients' expectations of hip and knee arthroplasty fulfilled? A prospective study of 130 patients. Orthopedics. 2010;33(2):76–80.

[874] Ghomrawi H.M., Franco Ferrando N., Mandl L.A., Do H., Noor N., Gonzalez Della Valle A. How Often are Patient and Surgeon Recovery Expectations for Total Joint Arthroplasty Aligned? Results of a Pilot Study. HSS journal: The musculoskeletal journal of Hospital for Special Surgery. 2011;7(3):229–234.

[875] Harris I.A., Harris A.M., Naylor J.M., Adie S., Mittal R., Dao A.T. Discordance between patient and surgeon satisfaction after total joint arthroplasty. The Journal of arthroplasty. 2013;28(5):722–727.

[876] Jourdan C., Poiraudeau S., Descamps S., et al. Comparison of patient and surgeon expectations of total hip arthroplasty. PloS one. 2012;7(1):e30195.

[877] Roos E.M. Effectiveness and practice variation of rehabilitation after joint replacement. Current opinion in rheumatology. 2003;15(2):160–162.

[878] Anderson F.A, Jr., Huang W., Friedman R.J., Kwong L.M., Lieberman J.R., Pellegrini V.D., Jr. Prevention of venous thromboembolism after hip or knee arthroplasty: findings from a 2008 survey of US orthopedic surgeons. The Journal of arthroplasty. 2012;27(5):659–666 e655.

[879] American Academy of Orthopaedic Surgeons (AAOS). Preventing Venous Thromboembolic Disease in Patients Undergoing Elective Hip and Knee Arthroplasty: Evidence-Based Guideline and Evidence Report. 2011.

[880] Suter L.G., Grady J.N., Lin Z., et al. 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/OR Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). March 2013.

[881] Suter L.G., Parzynski C.S., Grady J.N., et al. 2013 Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) AND/OR Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 2.0). March 2013; Available at: *http://qualitynet.org/*.

experience documents wide hospital-level variation in patient-reported outcome measure results following THA and TKA.[882]

For example, data from the United Kingdom demonstrate that there is a greater than 15 percent difference across hospitals in the proportion of patients showing improvement after surgery.[883] [884]

Peri-operative care and care coordination across provider groups and specialties have important effects on clinical outcomes.[885] [886] The goal of a hospital-level outcome measure is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patients' health and reducing the burden of their disease. THA and TKA procedures provide a suitable environment for optimizing care, as there are many studies indicating how hospitals and providers can improve outcomes of their patients by addressing aspects of pre-, peri-, and post-operative care.[887] [888] [889] [890] [891] [892]

Due to the absence of large scale and uniformly collected patient-reported outcome (PRO) data available from patients undergoing elective primary THA/TKA, in November 2015 we established an incentivized, voluntary PRO data collection opportunity within the Comprehensive Care for Joint Replacement (CJR) model [893] to support measure development. Requirements for successful submission of PRO data for eligible elective primary THA/TKA procedures were set forth in the 2015 CJR final rule (80 FR 73274). This Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) performance measure (THA/TKA PRO–PM) was developed and tested using PRO instruments and risk variable data collected and submitted by CJR participant hospitals. PRO data from the first few performance years for the CJR model revealed hospital-level variation in these outcomes across U.S. hospitals, although the full degree and extent of variation is unknown.

In October 2017, we launched the Meaningful Measures Framework to identify high priority areas for quality measurement that improve patient outcomes while also reducing burden on providers.[894] The initiative captures the agency's vision in evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The scope of the Meaningful Measures Framework continues to evolve as the healthcare environment continues to change. Meaningful Measures 2.0 [895] is currently underway and aims to promote better collection and integration of patients' voices by incorporating patient reported outcome measures that are embedded into the clinical workflow, are easy to use, and reduce reporting burden.[896] The THA/TKA PRO–PM is fully developed and aligns with these future Meaningful Measures 2.0 goals, which are still under development.

Elective THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (such as pain, mobility, and quality of life) can be measured in a scientifically soundway,
[897] [898] [899] [900] [901] [902] [903] [904] [905] [906] [907] [908] [909]
are influenced by a range of

[882] Rolfson O. Patient-reported Outcome Measures and Health-economic Aspects of Total Hip Arthroplasty: A study of the Swedish Hip Arthroplasty Register. (2010). *https://gupea.ub.gu.se/bitstream/handle/2077/23722/gupea_2077_23722_1.pdf?sequence=1.* Accessed July 20, 2013.

[883] National Health System: The Information Centre for Health and Social Care. HESonline Hospital Episode Statistics: Proms Data. *http://www.hesonline.nhs.uk/Ease/* ContentServer?siteID=1937&categoryID=1295, 2012.

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[892] Moffet H, Collet J.P., Shapiro S.H., Paradis G., Marquis F., Roy L. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: A single-blind randomized controlled trial. Archives of physical medicine and rehabilitation. 2004;85(4):546–556.

[893] Centers for Medicare & Medicaid Services. Comprehensive Care for Joint Replacement Model. Available at: *https://innovation.cms.gov/innovation-models/cjr.*

[894] CMS' Meaningful Measures Framework can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[895] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[896] *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

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[905] Papalia R., Del Buono A., Zampogna B., Maffulli N., Denaro V. Sport activity following joint arthroplasty: A systematic review. Br Med Bull. 2012;101:81–103.

[906] Rolfson O., Rothwell A., Sedrakyan A., et al. Use of patient-reported outcomes in the context of different levels of data. J Bone Joint Surg Am. 2011;93 Suppl 3:66–71.

[907] Suter L.G., Potteiger J., Cohen D.B., Lin Z., Drye E.E., Bernheim S.M. Environmental Scan/Literature Review: Total Hip and Total Knee Arthroplasty Patient-Reported Outcome Measure. Report prepared for Centers for Medicare & Medicaid Services. 2012.

[908] Thorborg K., Roos E.M., Bartels E.M., Petersen J., Holmich P. Validity, reliability and responsiveness of patient-reported outcome questionnaires when assessing hip and groin disability: A systematic review. BJSM online. 2010;44(16):1186–1196.

[909] White D., Master H. Patient Reported Measures of Physical Function in Knee Osteoarthritis. Rheum Dis Clin North Am. 2016;42(2):239–252.

improvements in care,[910] [911] [912] [913] [914] [915] [916] [917] and demonstrate hospital-level variation even after patient case mix adjustment.[918] [919] Further, THA/TKA procedures are specifically intended to improve function and reduce pain, making patient reported outcomes a meaningful outcome metric to assess.[920]

Several stakeholder groups were engaged throughout the development process of the THA/TKA PRO–PM, as recommended in the Measures Management System (MMS) Blueprint,[921] including a Technical Advisory Group (TAG), a Patient Working Group, and a national, multi-stakeholder TEP consisting of a diverse set of stakeholders, including providers and patients. These groups were convened by the measure developer under contract with CMS and provided feedback on the measure concept, outcome, cohort, risk model variables, reporting results, and data collection. We received feedback from patients and providers that they had a desire for a flexible data collection approach. For example, providers wanted the option to choose to collect their own data or have data collected through an external entity, such as a vendor. Patients wanted to choose from multiple modes of data collection, such as telephone, paper, and/or electronic. We also received feedback from patients and providers that they would like to utilize their patient reported outcome results as part of the shared decision-making process. Patients were more willing to report data if they knew the survey was from their provider, they understood the importance and use of the survey, and they had access to their own survey responses. In response to this feedback, we did not propose a specific mode for data collection for the THA/TKA PRO–PM. Rather, we proposed that hospitals may determine a data collection mode that accommodates their clinical workflow. We also received multiple public comments as summarized in the 2015 CJR final rule (80 FR 73274) that we used to support the development of this measure.

The THA/TKA PRO–PM (MUC20–0003) was included in the publicly available ''2020 Measures Under Consideration List.'' [922] The MAP Coordinating Committee supported the measure, as referenced in the 2020–2021 Final Recommendations report to HHS and CMS.[923] The NQF endorsed the THA/TKA PRO–PM (NQF #3559) in November 2020.[924]

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25588 through 25592), we requested public comment on the potential future inclusion of the THA/TKA PRO–PM in the Hospital IQR Program. Many commenters expressed support for the measure, with many commending joint-specific PRO–PMs as an effective way to provide insights to quality improvement opportunities, PRO–PMs for assessing results of surgery as interpreted by patients, and describing the measure as essential for value-based payment models (86 FR 45411 through 45414). Many commenters recommended that the measure be implemented in a phased approach, with voluntary reporting occurring prior to public reporting (86 FR 45411 through 45414). In response to these comments, we proposed a phased implementation approach, with two voluntary reporting periods in CY 2025 and 2026 reporting periods prior to mandatory reporting beginning with the CY 2027 reporting period/FY 2028 payment determination, as described in further detail in our discussion on data submission in section IX.E.5.g.(9).

Furthermore, many commenters recommended that we offer multiple options for data submission, including through the hospital directly or by an external vendor engaged by a hospital for this purpose, to ensure hospitals have the flexibility needed to implement the measure (86 FR 45411 through 45414). In response to those comments, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28526 through 28529), we proposed flexible options for data submission as discussed in more detail in subsequent section. For a more detailed description of the public comments received, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414).

Additionally, we note that many hospitals have already incorporated PRO data collection into their workflows. While we did not propose to require how hospitals collect data, hospitals new to collecting PRO data have multiple options for when and how they will collect this data and can best determine the mode of data collection that works for their patient population.

(2) Overview of Measure

The THA/TKA PRO–PM reports the hospital-level risk-standardized improvement rate (RSIR) in patient reported outcomes following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older.

Substantial clinical improvement will be measured by achieving a pre-defined improvement in score on joint-specific PRO instruments measuring hip or knee pain and functioning, from the pre-operative assessment (data collected 90 to 0 days before surgery) to the post-operative assessment (data collected 300 to 425 days following surgery). For additional details regarding the measure specifications, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—

[910] Brown K., Topp R., Brosky J.A., Lajoie A.S. Prehabilitation and quality of life three months after total knee arthroplasty: A pilot study. Perceptual and motor skills. 2012;115(3):765–774.

[911] Choong P.F., Dowsey M.M., Stoney J.D. Does accurate anatomical alignment result in better function and quality of life? Comparing conventional and computer-assisted total knee arthroplasty. The Journal of arthroplasty. 2009;24(4):560–569.

[912] Galea M.P., Levinger P., Lythgo N., et al. A targeted home- and center-based exercise program for people after total hip replacement: A randomized clinical trial. Arch Phys Med Rehabil. 2008;89(8):1442–1447.

[913] Kim K., Anoushiravani A., Chen K., et al. Perioperative Orthopedic Surgical Home: Optimizing Total Joint Arthroplasty Candidates and Preventing Readmission. Journal of Arthroplasty. 2019;34(7):S91–S96.

[914] McGregor A.H., Rylands H., Owen A., Dore C.J., Hughes S.P. Does preoperative hip rehabilitation advice improve recovery and patient satisfaction? The Journal of arthroplasty. 2004;19(4): 464–468.

[915] Moffet H., Collet J.P., Shapiro S.H., Paradis G., Marquis F., Roy L. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: A single-blind randomized controlled trial. Arch Phys Med Rehabil. 2004;85(4):546–556.

[916] Monticone M., Ferrante S., Rocca B., et al. Home-based functional exercises aimed at managing kinesiophobia contribute to improving disability and quality of life of patients undergoing total knee arthroplasty: A randomized controlled trial. Arch Phys Med Rehabil. 2013;94(2):231–239.

[917] Walters M., Chambers M., Sayeed Z., Anoushiravani A., El-Othmani M., Saleh K. Reducing Length of Stay in Total Joint Arthroplasty Care. Orthopedic Clinics of North America. 2016;47(4):653–660.

[918] Bozic K.J., Grosso L.M., Lin Z., et al. Variation in hospital-level risk-standardized complication rates following elective primary total hip and knee arthroplasty. JBJS. 2014;96(8):640–647.

[919] Ma kela K.T., Peltola M., Sund R, Malmivaara A., Ha kkinen U., Remes V.. Regional and hospital variance in performance of total hip and knee replacements: A national population-based study. Annals of medicine. 2011;43(sup1):S31–S38.

[920] Liebs T., Herzberg W., Gluth J., et al. Using the patient's perspective to develop function short forms specific to total hip and knee replacement based on WOMAC function items. Bone Joint J. 2013;95(B):239–243.

[921] Centers for Medicare & Medicaid Services. (2021). CMS Measures Management System Blueprint (Blueprint v 17.0). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.*

[922] 2020 Measures Under Consideration List. Available at *https://www.cms.gov/media/492911.*

[923] MAP 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. NQF. 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94894.*

[924] NQF Quality Positioning System. Available at *https://www.qualityforum.org/QPS.*

Measure Methodology Report, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

(3) Data Sources

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. The measure uses PRO data collected by hospitals pre-operatively and post-operatively (described in section IX.E.5.g.(9).) and limited patient-level risk factor data collected with PRO data and identified in claims. The measure includes PRO data collected with several PRO instruments, among them are two joint-specific PRO instruments—the Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) [925] for completion by THA recipients and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) [926] for completion by TKA recipients—from which scores are used to assess substantial clinical improvement. For risk adjustment by pre-operative mental health score, hospitals will submit one of two additional PRO instruments, either all of the items in the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global Mental Health subscale or all of the items in the Veterans RAND 12-Item Health Survey (VR–12) Mental Health subscale.[927] [928] The risk model also includes a one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, the following data are collected for identification of the measure cohort, outcome and for risk adjustment purposes. Claims data are used to identify eligible elective primary THA/TKA procedures for the measure cohort to which submitted PRO data can be matched, and to identify additional variables for risk adjustment and in the statistical approach to accounting for response bias, including patient demographics and clinical comorbidities up to 12 months prior to surgery. The Medicare Enrollment Database (EDB) identifies Medicare FFS enrollment and race, and the Master Beneficiary Summary File allows for determination of Medicare and Medicaid dual eligibility enrollment status. Demographic information from the U.S. Census Bureau's American Community Survey [929] allows for derivation of the AHRQ SES Index score. Race, dual eligibility, and AHRQ SES Index score are used in the statistical approach to accounting for non-response bias. We refer readers to section IX.E.5.g.(9). for further details regarding the variables required for data collection and submission.

(4) Outcome

The measure outcome (numerator) is the risk-standardized proportion of patients undergoing elective primary THA/TKA who meet or exceed a substantial clinical improvement threshold between pre-operative and post-operative assessments on two joint-specific PRO instruments. The measure outcome will assess patient improvement in PROs using the HOOS, JR following elective primary THA and the KOOS, JR following elective primary TKA. PRO data will be collected 90 to zero days prior to surgery and 300 to 425 days following surgery. These PRO collection periods align with typical patient visits prior to and following surgery.

The measure outcome defines patient improvement as a binary outcome (''Yes''/''No'') of meeting or exceeding the pre-defined improvement threshold between pre-operative and post-operative assessments on the joint-specific PRO instruments: Specifically, for THA patients, meeting or exceeding the threshold of 22 points on the HOOS, JR and, for TKA patients, meeting or exceeding the threshold of 20 points on the KOOS, JR.

(5) Cohort

The measure cohort (denominator) is Medicare FFS beneficiaries aged 65 years and older undergoing elective primary THA/TKA procedures as inpatients in acute care hospitals. We are aware that elective primary THA/TKA procedures are increasingly occurring in hospital outpatient and ambulatory surgical center settings and we will be evaluating options to address measurement of those procedures and settings.

For additional details regarding the measure cohort, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

(6) Inclusion and Exclusion Criteria

The THA/TKA PRO–PM includes patients who are:

- Enrolled in Medicare FFS Part A and Part B for the 12 months prior to the date of the index admission and enrolled in Part A during the index admission;
- Aged 65 or older; and
- Discharged alive from a non-Federal short-term acute care hospital.

The measure includes only elective primary THA/TKA procedures (patients with fractures and revisions are not included). The measure excludes patients with staged procedures, defined as more than one elective primary THA or TKA performed on the same patient during distinct hospitalizations during the measurement period, and patients who leave the hospital against medical advice following the procedure.

(7) Risk Adjustment

The risk model was developed with clinically relevant risk variables identified by public comment in the 2015 CJR final rule (80 FR 73274), the TEP, and expert orthopedic consultants, and supported by empirical analyses. The risk model includes some of the same risk variables collected with PRO data by hospitals in the CJR model as well as risk variables identified in claims. The pre-operative score of the Mental Health subscale from one of two global PRO instruments (the PROMIS-Global or the VR–12) is included as a risk variable. In addition, the risk model includes a validated, one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, poorly or incompletely collected PRO data may be asymmetrically distributed across lower socioeconomic or disadvantaged populations, potentially affecting measure scores. Research on PRO–PM response has indicated that patients of non-White race, patients of lower socio-economic status, and patients with

[925] Lyman S., Lee Y–Y., Franklin P.D., Li W., Mayman D.J., Padgett D.E. Validation of the HOOS, JR: A Short-form Hip Replacement Survey. *Clinical Orthopaedics and Related Research®*. 2016;474(6):1472–1482.

[926] Lyman S., Lee Y–Y., Franklin P.D., Li W., Cross M.B., Padgett D.E. Validation of the KOOS, JR: A Short-form Knee Arthroplasty Outcomes Survey. *Clinical Orthopaedics and Related Research®*. 2016;474(6):1461–1471.

[927] National Institutes of Health (NIH). (Patient Reported Outcomes Measurement Information Systems) PROMIS Instrument Details. Available at: *https://www.healthmeasures.net/explore-measurement-systems/promis.*

[928] Iqbal U.S., Rogers W., Selim A., et al. The Veterans Rand 12 Item Health Survey (VR–12): What It Is and How It Is Used. *http://www.hosonline.org/globalassets/hos-online/publications/veterans_rand_12_item_health_survey_vr-12_2007.pdf*.

[929] American Community Survey, available at: *https://www.census.gov/programs-surveys/acs.*

Medicare and Medicaid coverage have lower response rates.[930] [931] [932] Therefore, the measure developer used empirical analyses and stakeholder input to develop an approach to account for response bias in the measure calculation. The approach uses comorbidities, social drivers of health, and demographic variables (such as non-White individuals, dual eligibility, and AHRQ SES index lowest quartile) to predict response to the PRO survey. Weighting the responders based on their likelihood of response (given their patient characteristics) helps reduce non-response bias when calculating the RSIR.

For additional details regarding the approach to risk adjustment and the full risk model, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

(8) Measure Calculation

The hospital-level THA/TKA PRO–PM measure result is calculated by aggregating all patient-level results across the hospital. At the hospital level, this measure will be calculated and presented as a RSIR, producing a performance measure per hospital which accounts for patient case mix, addresses potential non-response bias, and represents a measure of quality of care following elective primary THA and TKA. Response rates for PRO data will be calculated as the percentage of elective primary THA or TKA procedures for which complete and matched pre-operative and post-operative PRO data have been submitted divided by the total number of eligible THA or TKA procedures performed at each hospital.

(9) Data Submission

Comments submitted on a request for information in the FY 2022 IPPS/LTCH PPS proposed rule and summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414) recommended CMS provide multiple options for data submission mechanisms to ensure flexibility, including through qualified clinical data registries, as well as through the hospital.

In response to ongoing stakeholder feedback and public comments in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414), we proposed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28527) to adopt the THA/TKA PRO–PM in the Hospital IQR Program utilizing multiple submission approaches. For example, hospitals may choose to: (1) Send their data to CMS for measure calculation directly; or (2) utilize an external entity, such as through a vendor or registry, to submit data on behalf of the hospital to CMS for measure calculation. Furthermore, hospitals or vendors will use the HQR System as part of data submission for the THA/TKA PRO–PM. Use of the HQR System leverages existing CMS infrastructure already utilized for other quality measures (such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey). The HQR System allows for data submission using multiple file formats (such as CSV, XML) and a manual data entry option, allowing hospitals and vendors additional flexibility in data submission. We will provide hospitals with more detailed instructions and information regarding data submission through CMS' existing website QualityNet, and through list servs. This data submission approach is consistent with stakeholder input received by the measure developer during measure development and comments as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414) which recommended CMS provide multiple options for data submission mechanisms to ensure flexibility.

Hospitals will submit the following pre-operative assessment variables collected between 90 and zero days prior to the THA/TKA procedure: Medicare provider number, Medicare health insurance claim (HIC) number/Medicare beneficiary identifier (MBI), date of birth, date of procedure, date of PRO data collection, procedure type, mode of collection, person completing the survey, date of admission to anchor hospitalization, generic patient reported outcome measure version, PROMIS-Global (mental health subscale items) or VR–12 (mental health subscale items), HOOS, JR (for THA patients), KOOS, JR (for TKA patients), Single-Item Health Literacy Screening (SILS2) questionnaire, BMI or weight (kg)/height (cm), chronic (≥ 90 day) narcotic use, total painful joint count (patient-reported in non-operative lower extremity joint), and quantified spinal pain (patient-reported back pain, Oswestry index question[933] [934]).

Hospitals will submit the following post-operative assessment variables collected between 300 and 425 days following the THA/TKA procedure: Medicare provider number, Medicare health insurance claim number/Medicare beneficiary identifier, date of birth, procedure date, date of PRO data collection, procedure type, mode of collection, person completing the survey, date of admission to anchor hospitalization, KOOS, JR (TKA patients), and HOOS, JR (THA patients). The data submission period for the THA/TKA PRO–PM will also serve as the review and correction period. Data will not be able to be corrected following the submission deadline.

For additional details we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

(a) Voluntary Reporting Period

[930] Hutchings A., Neuburger J., Frie K., Black N., van der Meulen J. Factors associated with nonresponse in routine use of patient reported outcome measures after elective surgery in England. Health and Quality of Life Outcomes. 2012;10(34).

[931] Schamber E., Takemoto S., Chenok K., Bozic K. Barriers to completion of patient reported outcome measures. The Journal of arthroplasty. 2013;28:1449–1453.

[932] Patel J., Lee J., Zhongmin L., SooHoo N., Bozic K., Huddleston J. Predictors of low patient-reported outcomes response rates in the California Joint Replacement Registry. The Journal of arthroplasty. 2015;30:2071–2075.

[933] Fairbank J.C., Pynsent P.B. The Oswestry Disability Index. Spine (Phila Pa 1976). 2000 Nov 15;25(22):2940–52; discussion 2952. doi: 10.1097/00007632–200011150–00017. PMID: 11074683.

[934] The Oswestry Disability Index is in the public domain and available for all hospitals to use.

We proposed a phased implementation approach for adoption of this measure to the Hospital IQR Program, with two voluntary reporting periods prior to mandatory reporting in the Hospital IQR Program. Voluntary reporting prior to mandatory reporting will allow time for hospitals to incorporate the THA/TKA PRO–PM data collection into their clinical workflows and is responsive to stakeholder comments as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414). For each voluntary and subsequent mandatory reporting period, we will collect data on the THA/TKA PRO–PM in accordance with, and to the extent permitted by, the HIPAA Privacy and Security Rules (45 CFR parts 160 and 164, subparts A, C, and E), and other applicable law.

We proposed that the first voluntary reporting period for CY 2025 would include pre-operative PRO data collection from October 3, 2022 through June 30, 2023 (for eligible elective primary THA/TKA procedures performed from January 1, 2023 through June 30, 2023) and post-operative PRO data collection from October 28, 2023 to August 28, 2024. Hospitals will submit pre-operative data in 2023 and post-operative data in 2024, and we intend to provide hospitals with their results in confidential feedback reports in 2025. We refer readers to section IX.E.10.k., where we discuss the form, manner, and timing for PRO–PMs, including submission deadlines.

The second voluntary reporting period for CY 2026 will include pre-operative PRO data collection from April 2, 2023 through June 30, 2024 (for eligible elective primary THA/TKA procedures performed from July 1, 2023 through June 30, 2024) and post-operative PRO data collection from April 26, 2024 to August 29, 2025. Hospitals will submit pre-operative data in 2024 and post-operative data in 2025, and we intend to provide hospitals with their results in confidential feedback reports in 2026. We refer readers to section IX.E.10.k., where we discuss the form, manner, and timing for PRO–PMs, including submission deadlines.

Hospitals that voluntarily submit data for this measure will receive confidential feedback reports that detail submission results from the reporting period. If feasible, we will calculate and provide each participating hospital with their risk-standardized improvement rate as part of the confidential feedback reports. This will provide each hospital with an indication of their performance relative to the other hospitals that participate in the voluntary reporting period. We refer readers to Table IX.E–07. for an overview of the pre- and post-operative performance periods, data collection windows, and data submission deadlines during voluntary reporting.

TABLE IX.E-07. PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM FOR VOLUNTARY REPORTING

Reporting Period	Performance Period	Pre-operative Data Collection Window	Pre-operative Data Submission Deadline	Post-operative Data Collection Window	Post-operative Data Submission Deadline
Voluntary Reporting 1 (2025)	January 1, 2023 through June 30, 2023	October 3, 2022 through June 30, 2023	October 2, 2023	October 28, 2023 to August 28, 2024	September 30, 2024
Voluntary Reporting 2 (2026)	July 1, 2023 through June 30, 2024	April 2, 2023 through June 30, 2024	September 30, 2024	April 26, 2024 to August 29, 2025	September 30, 2025

(b) Mandatory Reporting

Following the two voluntary reporting periods, we proposed that mandatory reporting of the THA/TKA PRO–PM would begin with eligible elective primary THA/TKA procedures from July 1, 2024 through June 30, 2025 with affecting the FY 2028 payment determination. Hospitals' data reporting requirements will be based on pre-operative PRO data collection from April 2, 2024 through June 30, 2025 (for eligible elective THA/TKA procedures from July 1, 2024 through June 30, 2025) and post-operative PRO data collection from April 27, 2025 to August 29, 2026. Pre-operative data submission will occur in 2025 and post-data submission in 2026 and we intend to provide hospitals with their results in 2027 before publicly reporting results on the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*, or its successor website. For this first mandatory reporting period, hospitals that fail to timely meet the reporting requirements will receive a reduction of their Annual Payment Update (APU) in FY 2028. We refer readers to the section IX.E.10.k., where we discuss the form, manner, and timing for PRO–PMs, including submission deadlines. We refer readers to Table IX.E–08. for an overview of the pre- and post-operative performance periods, data collection windows, and data submission deadlines during mandatory reporting.

TABLE IX.E-08. PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM FOR MANDATORY REPORTING

Reporting Period	Performance Period	Pre-operative data Collection Window	Pre-operative Data Submission Deadline	Post-operative Data Collection Window	Post-operative Data Submission Deadline
Mandatory Reporting (2027)	July 1, 2024 through June 30, 2025	April 2, 2024 through June 30, 2025	September 30, 2025	April 27, 2025 to August 29, 2026	September 30, 2026

(10) Public Reporting

(a) Voluntary Reporting Periods

We proposed to provide hospitals with their THA/TKA PRO–PM results in confidential feedback reports during the two voluntary reporting periods occurring in 2025 and 2026. While we did not propose to publicly report voluntary THA/TKA PRO–PM hospital-level risk-standardized improvement rates (RSIR) during this period, to acknowledge the efforts of stakeholders who choose to participate in voluntary reporting, and to support their efforts to improve quality in this important area, we proposed to publicly report which hospitals choose to participate in voluntary reporting and/or the percent of pre-operative data submitted by participating hospitals for the first voluntary reporting period, and their percent of pre-operative and post-operative matched PRO data submitted for subsequent voluntary reporting periods. For example, if out of 100 eligible procedures a hospital submits 45 pre-operative cases that match to post-operative cases, then we will report that hospital submitted 45 percent of matched pre-operative and post-operative PRO surveys during voluntary reporting

(b) Mandatory Reporting

The THA/TKA PRO–PM results and response rates will be publicly reported on the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*, or its successor website, beginning with the first mandatory reporting period for the FY 2028 payment determination. Reporting will be based on pre-operative PRO data April 2, 2024 through June 30, 2025 (for eligible elective THA/TKA procedures from July 1, 2024 through June 30, 2025) and post-operative PRO data collection from April 27, 2025 to August 29, 2026. Hospitals will receive confidential feedback reports prior to public reporting that detail results from the reporting period. If feasible, confidential feedback reports will include the risk-standardized improvement rate as well as other results that support understanding of their performance.

We invited public comment on this proposal.

Comment: Many commenters expressed support for the adoption of the THA/TKA PRO–PM in the Hospital IQR Program. A commenter strongly supported the adoption of the measure as it provides patients with valuable information on the quality of joint care provided by hospitals, as well as information on post-operative functional improvements. Another commenter strongly supported the adoption of the measure as it assesses the success of procedures based on outcomes that are important to patients while also supplying clinical teams with information essential to a patient's recovery. The commenter noted this information is useful to other patients seeking care and should be publicly posted. A commenter stated patient-reported outcomes for elective primary THA and TKA procedures are critical to ensure the procedure quality is accurately captured. Another commenter supported the measure's adoption as it incentivizes collaboration in patient care between hospitals and providers, both pre- and post-operatively, which improves patient outcomes. Many commenters expressed support for the collection of PRO data for hospital quality improvement efforts, and use of PRO–PMs in CMS programs, generally. A commenter stated that THA and TKA procedures offer the majority of patients significant improvement in quality of life by decreasing pain and improving function without high risk of complication or death and, therefore, supported collection of PRO data for total joint replacements. A commenter supported adoption of the measure for Critical Access Hospitals that provide THA and TKA services. A commenter supported the adoption of the measure and requested more information on the mechanism for data collection for providers and patients.

Response: We thank commenters for their support and agree with the importance of measuring patient-reported outcomes for elective primary THA and TKA procedures, particularly to measure functional improvement following the applicable surgical procedure. We will conduct education and outreach activities for hospitals and other stakeholders with detailed information, including data collection and reporting processes for the THA/TKA PRO–PM to support preparation for the voluntary reporting periods in the Hospital IQR Program.

Comment: Many commenters did not support the proposed adoption of the THA/TKA PRO–PM to the Hospital IQR Program because of the volume of newly proposed quality measures and EHR-related reporting requirements proposed by CMS for the Hospital IQR Program. Many commenters expressed concern that the adoption of the THA/TKA PRO–PM to the Hospital IQR Program would be burdensome to hospitals. Many commenters stated that the financial, resource, and labor costs required to collect, track, and submit data would burden hospitals and make successful implementation of the measure difficult, even if hospitals opt to use a third-party vendor for data collection and submission. A commenter expressed concern about the burden specifically for small and rural hospitals. A few commenters noted that data are not collected in a standardized way and EHRs are not integrated with patient portals that would allow hospitals to collect patient-reported information, adding manual burden to extrapolate data or infrastructure investments. A commenter noted their belief that the measure is counter to CMS's efforts to reduce administrative burden for hospitals and detracts from their primary mission of direct patient care. A few commenters urged CMS to work with stakeholders to develop a less burdensome measure or reassess the burden compared to the value of this measure following voluntary reporting.

A few commenters expressed concerns regarding the burden of tracking patients pre- and post-operatively to collect PRO data, stating that data are not centrally housed, patients receive post-operative care outside the hospital, and the tracking of patients for the duration of the post-operative data collection timeframe of 300 to 425 days would be expensive and burdensome. Additionally, a few commenters stated that reaching out to patients to collect surveys in multiple modes would be expensive; however, other commenters encouraged having multiple modes of survey collection.

Response: We acknowledge commenters' concerns with the volume of measures and reporting requirements proposed for the Hospital IQR Program. We will continue to evaluate the Hospital IQR Program measure set and take this feedback into consideration. However, we believe that measuring patient-reported outcomes is an important aspect of patient-centered healthcare and continue to emphasize, as highlighted in our Meaningful Measures 2.0 Framework,[935] that the patient voice should be prioritized across healthcare systems and providers. Our aim is to promote better collection and integration of patients' voices by incorporating PROMs that are embedded into clinical workflow, easy to use, and as minimally burdensome to patients and providers as possible.

We thank commenters for their feedback regarding the financial, labor, and resource burdens associated with adopting the THA/TKA PRO–PM to the Hospital IQR Program. We acknowledge

[935] *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.*

that while PROMs and PRO–PMs may involve more burden and initial implementation resources compared to some other types of quality measures, we believe the benefit of collecting direct functional improvement information from the patients outweighs the burden. We are carefully considering public comments and are seeking to advance patient-centered measurement with as little burden as possible to both providers and patients. While PRO–PMs require providers to integrate data collection into clinical workflows, this integration provides an important opportunity for patient-reported outcomes to inform clinical decision making and benefit patients by engaging them in discussions about potential outcomes. To provide more flexibility, we are not requiring hospitals to collect data in a standardized way. In fact, we acknowledge hospitals may use a variety of data collection, storage, and submission approaches, and we encourage hospitals to use processes best suited to them. Instead, we are standardizing the specific data elements that need to be collected and reported to CMS. Further, we believe that clinicians, providers, and hospitals should determine practices that avoid duplication across care settings. We will continue to monitor data collection burden and duplication during the voluntary reporting period.

The PRO instruments used to calculate pre- and post-operative scores for this THA/TKA PRO–PM were carefully considered, with extensive stakeholder input, including from clinicians, to be low burden and are non-proprietary for free use. We will evaluate data collection burden and response rates associated with the THA/TKA PRO–PM and will also consider this information in future measure reevaluation.

Comment: A few commenters expressed concern about the data collection burden for patients, with a commenter specifically citing survey fatigue as patients are already responding to the HCAHPS survey measure. Another commenter expressed concern that completion of surveys for the measure beyond only the HOOS, JR and KOOS, JR would burden patients resulting in lower completion rates.

Response: This measure was developed with extensive input from patients, who indicated strong support for a PRO–PM following elective primary THA and TKA. We anticipate data collection for this measure to present a low burden to patients. Regarding survey fatigue, we designed the measure to illuminate a patient's pain and functional status before and after a THA or TKA, which is different than other surveys such as HCAHPS that capture patient experience. Regarding the comment that the THA/TKA PRO–PM may have a reporting impact on other measures, such as HCAHPS, we anticipate a minimal impact to other measures as the THA/TKA PRO–PM's eligible population is procedure-specific which reduces the likelihood of the same patient receiving the HCAHPS and a PRO survey. Additionally, the THA/TKA PRO–PM pre-operative assessment (90 to 0 days before surgery) and post-operative assessment (300 to 425 days following surgery) timeframe is different than HCAHPS, which is two weeks after a hospital visit.

Comment: Another commenter requested CMS assess survey completion rates during voluntary reporting of the measure as part of the Hospital IQR Program compared to the CJR Model. A few commenters requested CMS not adopt the THA/TKA PRO–PM in the Hospital IQR Program until operational challenges identified by CJR participating hospitals are shared publicly, independently analyzed, and addressed. Commenters expressed concern that reporting of the THA/TKA PRO–PM as part of the CJR Model has been challenging and burdensome, potentially impacting completion rates.

Response: We appreciate commenters' request for information about use of the measure in the CJR Model. We have collected feedback from CJR participating hospitals and applied lessons learned to the THA/TKA PRO–PM proposal for adoption into the Hospital IQR Program. These lessons learned include requiring hospitals to collect and submit fewer variables, allowing hospitals flexibility in data collection options to better integrate into their workflows, and influenced the decision to set the reporting threshold to a moderate rate of 50 percent. We highlight that our proposal includes two voluntary reporting periods in which we will gather feedback from participating hospitals on their experience collecting and submitting data and apply any lessons learned prior to mandatory reporting.

We thank commenters for their feedback. We will continue to evaluate feedback on challenges with data collection during voluntary reporting and consider them prior to mandatory reporting.

Comment: A few commenters suggested ways to reduce data collection and submission burden for hospitals and providers. A commenter suggested CMS align THA/TKA PRO–PM data collection with The Joint Commission Advanced Hip and Knee certification requirements. Another commenter suggested data collection should occur through registries, specifically the American Academy of Orthopedic Surgeons American Joint Replacement registry. A few commenters recommended CMS only use claims data or develop a new measure using Medicare claims to assess total joint arthroplasty revisions and mortality rates. A commenter recommended CMS directly collect post-operative surveys because CMS has access to current beneficiary information, could collect surveys for different surgeries across care settings, and reduce burden on providers.

Response: We thank commenters for their recommendations to reduce burden of data collection and submission associated with adoption of the THA/TKA PRO–PM to the Hospital IQR Program. We confirm that the measure as proposed notes registries as an acceptable form of data collection for the measure (87 FR 28527 through 28528). We agree with use of registries to reduce data collection burden for hospitals. Regarding alignment of the THA/TKA PRO–PM with The Joint Commission Advanced Hip and Knee certification requirements, we note that alignment exists in the PRO instruments, specifically the HOOS, JR and KOOS, JR (collected for the measure outcome for the THA/TKA PRO–PM) as well as the PROMIS–10 or VR–12 (collected for the risk model of the THA/TKA PRO–PM).[936] We will continue to monitor potential areas for alignment, as appropriate. We will also consider commenter suggestions about CMS's role in post-operative data collection, and the development of claims-based joint arthroplasty measures.

Comment: Many commenters expressed concerns with the 300 through 425 days post-operative data collection window related to appropriateness, feasibility, and burden to hospitals and other care settings, though a commenter supported assessment of longer-term outcomes generally. A few commenters stated that the proposed post-operative data collection window is not aligned with clinical practice where patients receive follow up care from their surgeons ranging between three to eight weeks post-operatively. A few commenters

[936] The Joint Commission. *R3 Report Issue 26: Advanced Total Hip and Total Knee Replacement Certification Standards;* 2020. *https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/thkr-standards-r3-final-copy-1_17_20.pdf.*

added that most improvement is demonstrated before the 300 through 425 post-operative data collection windows: for example, within 80 or 90 days. A commenter stated the proposed post-operative data collection window will introduce unnecessary health care encounters which add risk to patients. A few commenters noted challenges with tracking patients during the post-operative data collection window, stating beneficiaries do not always return for follow up care or may relocate. A commenter was concerned the post-operative data collection window was too far removed from the surgery and patient survey responses could be inaccurate. Several commenters recommended CMS shorten the post-operative data collection window. Commenters offered the following suggestions: 3 months, 3 through 6 months, and 8 through 12 months.

Response: We appreciate commenters' concerns with the 300 through 425-day post-operative data collection window; however, we disagree that the proposed post-operative window should be changed at this time. In development of the THA/TKA PRO–PM, the measure developer conducted extensive stakeholder engagement, a thorough literature review, and reviewed registry data capture to inform the post-operative assessment window (initially 270 to 365 days) for capture of full recovery from both THA and TKA and alignment with the typically scheduled one-year post-surgery appointments so that the collection of the post-operative data collection would not require an additional appointment. Following several years of PRO data collection through the CJR Model, clinical experts expressed concern that the initial 365-day upper limit missed patients who were scheduled or rescheduled for this one-year follow-up beyond 365 days, and they strongly advocated for shifting the post-operative data collection window to better align with clinical practice and increase PRO data collection. For additional details we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

Comment: Many commenters provided feedback on the proposed voluntary and mandatory reporting timelines for the THA/TKA PRO–PM adoption into the Hospital IQR Program but expressed a mix of support and recommended changes. A few commenters supported the proposed voluntary and mandatory reporting timelines, noting they give hospitals an opportunity to incorporate data collection into clinical workflows. However, a few commenters supported only the voluntary reporting timeline without mandatory reporting. A few commenters requested CMS extend the voluntary reporting timeline and delay mandatory reporting to support hospitals learning and their incorporation of data collection into clinical workflows; to allow CMS to assess the success, value, and burden of the measure; and to allow time for data collection challenges to be reduced. A commenter suggested four years of voluntary reporting. Another commenter recommended CMS use multiple six- month reporting periods before requiring a full year of reporting data.

Response: We thank commenters for their support of the phased approach of adopting the THA/TKA PRO–PM in the Hospital IQR Program. We have considered commenters' recommendations regarding voluntary and mandatory reporting timelines. We believe the proposed voluntary and mandatory reporting implementation approach will allow hospitals sufficient time to make the necessary enhancements to their clinical workflow to successfully report this measure. We highlight that our proposal includes two voluntary reporting periods prior to mandatory reporting which balances the need to allow hospitals time to prepare for mandatory reporting with the need to make this information public for patient use. We will carefully consider feedback received during voluntary reporting to inform improvements that may be made for mandatory reporting. We also refer readers to section IX.E.10.k. of this final rule where we discuss in more detail the form, manner, and timing of reporting the THA/TKA PRO–PM.

Comment: A few commenters did not support the adoption of the THA/TKA PRO–PM into the Hospital IQR Program as proposed. A commenter expressed that physician performance cannot be differentiated using patient-reported outcomes, noting many factors that influence an outcome are beyond an individual physician's influence, such as those related to patient factors and quality of care received overall.

Response: We acknowledge commenters' concerns regarding the adoption of the THA/TKA PRO–PM and patient-reported outcomes generally. However, we believe that PRO–PMs are an important aspect of patient-centered healthcare and continue to emphasize our position in our Meaningful Measures 2.0 Framework [937] that the patient voice is prioritized across healthcare systems and providers. Our aim is to promote better collection and integration of patients' voices by incorporating PRO–PMs that are embedded into clinical workflow, easy to use, and reduce reporting burden. We agree with the commenter that many factors influence a patient's outcome after a THA or TKA procedure, many of which are related to the overall quality of care the patient received at the hospital. As such, we are beginning to measure patient reported outcomes for these procedures at the hospital level but believe future measurement in other care settings, such as for HOPDs, ASCs, or at the clinician level, is important to understanding quality of care across settings.

Comment: Many commenters discussed the appropriateness of CMS' use of the THA/TKA PRO–PM in the hospital setting. A few commenters recommended CMS expand use of the measure across other care settings where THA/TKA procedures are performed. Many commenters noted the transition of THA/TKA procedures from the inpatient hospital setting to the outpatient setting and encouraged use of the measure in the Hospital Outpatient Quality Reporting (OQR) Program or the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, and at the clinician level, with a few commenters recommending CMS monitor shifts in volume of procedures between settings during the voluntary reporting period. A few commenters expressed concern that, given the shift of procedures to the outpatient setting, only the sickest and most complex patients would undergo THA/TKA procedures in the hospital, and this could skew hospital results on the measure. A few commenters suggested that CMS consider risk adjusting to account for trends in greater acuity of inpatient patients undergoing THA/TKA procedures. A few commenters had concerns attributing outcomes to hospitals because surgeons' offices or other settings commonly administer PRO surveys. Another commenter requested CMS consider its future public reporting approach to ensure inappropriate comparisons cannot be made between hospital and outpatient THA/TKA PRO–PM results.

[937] *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization*.

A commenter suggested CMS consider efficiencies gained by linking hospital data with MIPS data for providers.

Response: We thank commenters for their support for expanding this measure to other programs and settings. We agree that monitoring trends and transition of THA/TKA procedures to outpatient settings is also important. We appreciate commenter insights on the differences in patient complexity across care settings and will continue to monitor this during reevaluation of the measure's risk adjustment model. We disagree that the measure is not appropriate for the inpatient hospital setting at this time. We note that the proposed THA/TKA PRO–PM measure is case mix adjusted for patient comorbidities and is a relative performance measure for hospitals performing these elective THA and TKA procedures (87 FR 28527).[938] As such, we believe that this measure accurately reflects hospital performance even if patients receiving these procedures in the inpatient setting tend to be sicker, on average, than those treated in an outpatient setting.

Given the relatively recent removal of TKA and THA from the Inpatient Only (IPO) list (82 FR 52521 through 52526) (84 FR 61352 through 61355), we expect that the volume of THA and TKA procedures will continue to increase in HOPDs and ASCs, and that significant numbers of Medicare beneficiaries 65 and older will potentially undergo these procedures in the outpatient setting in future years. We recognize that potential future adoption and implementation of a respecified version of the THA/TKA PRO–PM in the Hospital OQR Program would require sufficient numbers of procedures for each measured HOPD and ASC to ensure a reliable measure score. We proposed the measure in the inpatient setting at this time and will consider potential expansion to other outpatient settings. We refer readers to the CY 2022 OPPS final rule for a summary of comments on the request for comment on the potential future adoption of the measure into the Hospital OQR and ASCQR Programs (86 FR 63851 through 63854 and 63896 through 63898). We also agree that there is value in measurement at the clinician level, however, the hospital level measure helps capture the quality of care provided during a patient's stay and provides the opportunity for more entities to have sufficient case volume to be included in the measure. A respecified version of the measure at the clinician level, the Clinician-Level and Clinician Group-Level Total Hip and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure, was included on the 2021 Measures Under Consideration List. For additional details we refer readers to the List of Measures Under Consideration for December 1, 2021 at: *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf*. Any proposal to implement the measure in other CMS programs would be announced through future rulemaking.

Comment: A few commenters provided recommendations on reimbursement and incentives for adopting the THA/TKA PRO–PM in the Hospital IQR Program. A commenter stated CMS should not use the measure in determining hospital reimbursement due to limits in risk stratification. Another commenter stated it is too early to compare hospital scores to determine reimbursement as PRO scores are not fully understood at the patient level. Another commenter urged CMS not to impose penalties if the measure is adopted. A few commenters recommended CMS provide incentives for hospitals to report the measure. Another commenter stated rural hospitals that are burdened by the measure would benefit from incentives similar to the facility bonus used in the Quality Payment Program (QPP). A few commenters encouraged CMS to consider reimbursing hospitals for data collection, such as using a CPT code with a bonus, similar to QPP. Another commenter recommended a quality bonus payment similar to the CJR Model or Bundled Payments for Care Improvement Initiative.

Response: We thank commenters for their recommendations about reimbursement and incentives for reporting the THA/TKA PRO–PM. We are not able to provide incentive payments under the Hospital IQR Program. We note that the Hospital IQR Program is a pay-for-reporting program, and hospitals' payments are not based on their performance on measures; hospitals will receive credit for the reporting of their measure data regardless of their measure score.

Comment: A few commenters provided recommendations regarding the measure specifications. A commenter supported the risk adjustment approach for the measure. However, another commenter recommended CMS include social determinants of health, body mass index, and smoking as risk variables and a third commenter requested CMS also consider variables that are outside of providers' influence that impact outcomes, such as patient adherence to surgical instructions or comorbidities. A few commenters recommended separating THA and TKA into their own procedure specific measures, stating that THA procedures have a higher success rate for improvement while the same level of improvement is not reached for TKA procedures. A few commenters suggested CMS calculate the change in PRO survey scores for individual patients pre- and post-operatively rather than the measure calculation approach as currently proposed. A commenter requested CMS exclude patients with history of prosthetic knee joint infections for reimplantation of knee arthroplasty and arthroplasties where the medical record includes a diagnosis of nonunion where the surgery is performed on a joint previously fractured that failed to heal. The commenter expressed concern that these surgeries are highly complex and dissimilar to other procedures captured in the THA/TKA PRO–PM's cohort as proposed.

Response: We thank commenters for their input on the THA/TKA PRO–PM's specifications for the cohort, risk adjustment, and measure calculation. We note that the measure is risk adjusted for several risk variables including but not limited to health literacy, body mass index, and several comorbidities (87 FR 28527). The threshold improvement approach to measure score calculation was strongly supported by clinical experts and patients during measure development and preferred to averaging patient change scores. We note that the National Quality Forum endorsed the THA/TKA PRO–PM as proposed.[939] For additional details we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*. We will review these recommendations and consider any adjustments to the measure as appropriate as part of normal ongoing measure reevaluation.

Comment: A few commenters provided input on the PRO instruments

[938] Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure (Version 1.0 Methodology Report). March 2021.

[939] National Quality Forum. Patient Experience and Function Final Report—Spring 2020 Cycle; 2021. Available at: *https://www.qualityforum.org/Publications/2021/03/Patient_Experience_and_Function_Final_Report_-_Spring_2020_Cycle.aspx*.

selected for the THA/TKA PRO–PM. A commenter requested CMS clarify rationale for collecting quantified spinal pain in the Oswestry Disability index. Another commenter opposed limiting the THA/TKA PRO–PM to just HOOS, JR and KOOS, JR instruments and suggested CMS allow communities to decide which validated PRO instrument to use for their patient population. The commenter noted the HOOS, JR and KOOS, JR lack cross cultural validation and suggested use of HOOS and KOOS full forms, Joint Replacement Shortforms, Physical Function Shortform, or PROMIS Physical Function.

Response: We thank commenters for their feedback on the selected PRO instruments. Use of the HOOS, JR and KOOS, JR instruments to calculate pre- and post-operative scores for this THA/TKA PRO–PM were carefully considered, with extensive stakeholder input from clinicians, and found to be low burden. The clinicians also believed, and data demonstrated, that joint-specific functional status tools such as the HOOS, JR and KOOS, JR are more relevant for clinical decision making and are more responsive than other PROMs that are not as specific. We believe the use of different PRO instruments by different facilities would prevent a valid comparison of hospital performance and quality. In response to the commenter's objection to collection of Quantified Spinal Pain as part of the Oswestry Disability index,[940] [941] we note that variable was identified as a clinical risk variable supported by the Technical Expert Panel and orthopedic experts as relevant and important for risk adjustment of outcomes following elective primary THA and TKA procedures. We note that the National Quality Forum endorsed the THA/TKA PRO–PM as proposed.[942] For additional details we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

Comment: A few commenters discussed concerns with the THA/TKA PRO–PM's impact on health disparities and response bias. A few commenters stated that surveys may only provide a limited sample of patient data, introducing bias and masking lower completion rates among marginalized groups. Surveys administered through technologies such as Epic, text, or third-party vendors could worsen racial disparities, introduce barriers, and limit a hospital's ability to collect a representative sample of patients from all races, socioeconomic statuses, and languages. A commenter questioned whether the THA/TKA PRO–PM as proposed adjusts for non-response bias for patients with limited English language proficiency, as such patients would be challenged to complete surveys, and hospitals with a high proportion of patients with limited English proficiency may have a lower response rate. A commenter suggested CMS provide reimbursement to hospitals to overcome these challenges in data collection. Another commenter encouraged stratification and reporting of results to hospitals for underrepresented populations.

Response: We thank commenters for their input regarding health disparities and response bias. We agree with commenters that considering the unique experience of populations with social risk factors is important. As proposed, the measure accounts for potential non-response bias (inverse probability weighting) and considers patient characteristics, including non-White race, dual eligibility, and the AHRQ SES index score (87 FR 28527). The AHRQ SES index score is computed using US census data and considers factors including zip code, median household income, percentage of persons below the Federal poverty line, unemployment, education, property value, and percentage of persons in crowded households.[943] Although preferred language spoken is not a variable currently included in the non-response bias approach, the measure as proposed includes health literacy in the risk model. For additional details we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*. We appreciate the comments regarding the importance of considering disadvantaged populations within the measure specifications and implementation, and we will continue to assess any impact of social risk factors on the measure and response rates over time.

Regarding non-response bias and the measure results, we encourage hospitals to consider a variety of PRO data collection methods to support responses from all eligible patients. We also recognize that addressing health disparities and response bias are complex issues. We are firmly committed to addressing health disparities and response bias for patient reported outcomes. We believe finalizing the Hospital Commitment to Health Equity structural measure and the two Social Drivers of Health screening measures, discussed in sections IX.E.5.a. and IX.E.5.b. of this final rule, respectively, supports addressing these issues and incentivizes structural quality improvement. We believe it will take a complementary set of quality measures focused on health equity to see significant improvements.

Comment: A few commenters expressed concern about reporting thresholds as well as the pre- and post-operative survey matching requirements. A commenter suggested CMS lower the reporting threshold for the measure and study response rates before finalizing a threshold. Another commenter urged CMS to use the voluntary reporting periods to set realistic matching percentages between pre- and post-operative surveys. A commenter noted the transition from performing THA and TKA procedures from hospitals to outpatient settings may affect hospital's ability to meet reporting thresholds. A commenter noted that the CJR Model uses an 80% reporting threshold which is challenging for hospitals to meet. The commenter encouraged CMS to analyze response rates from CJR participating hospitals and identify ways to increase pre- and post-operative survey responses. Another commenter questioned if hospitals will be penalized for not meeting reporting thresholds due to low response rates.

Response: We selected the 50 percent reporting threshold after considering numerous factors and the experience of CJR Model participants. The proposed reporting threshold is based on average response rates for both pre-operative

[940] Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine (Phila Pa 1976). 2000 Nov 15;25(22):2940–52; discussion 2952. doi: 10.1097/00007632–200011150–00017. PMID: 11074683.

[941] The Oswestry Disability Index is in the public domain and available for all hospitals to use.

[942] National Quality Forum. Patient Experience and Function Final Report—Spring 2020 Cycle; 2021. *https://www.qualityforum.org/Publications/2021/03/Patient_Experience_and_Function_Final_Report_-_Spring_2020_Cycle.aspx*.

[943] Bonito A, Bann C, Eicheldinger C, Carpenter L. Creation of new race-ethnicity codes and socioeconomic status (SES) indicators for Medicare beneficiaries. Final Report, Sub-Task. 2008;2.

and post-operative surveys collected by participating hospitals in the CJR Model. The proposed reporting threshold for adoption of the measure into the Hospital IQR Program is lower than that currently used in the CJR Model (50 percent versus 80 percent). Additionally, hospitals are not held to reporting thresholds until mandatory reporting; therefore, we believe hospitals will have time to develop their data collection and reporting processes. Lastly, the proposed thresholds for the Hospital IQR Program are percentages based on the number of eligible inpatient procedures performed by a hospital; therefore, we do not expect any potential future transition of procedures to outpatient settings to impact a hospital's ability to meet reporting thresholds (87 FR 28559 through 28560).

We will continue to consider the appropriate pre- and post-operative matched survey response rate, as well as reporting thresholds. We will evaluate our proposed approach during voluntary reporting and consider adjustments based on feedback prior to mandatory reporting.

Comment: A few commenters requested CMS adjust the threshold of functional improvement of 20 and 22 points for KOOS, JR and HOOS, JR, respectively. A commenter requested CMS to adopt an average functional gain for HOOS, JR and KOOS, JR scores to better capture the extent of patient-reported post-operative improvement, stating that the proposed approach sets the quality bar too low and is not aligned with the literature.

Response: The substantial clinical benefit thresholds of a 20-point improvement on the KOOS, JR and a 22-point improvement on the HOOS, JR were selected based on our analyses of published literature and measure development data and with considerable stakeholder input to capture variation in patient outcomes among hospitals that reflect differences in care quality among hospitals. During measure development, these improvement thresholds were supported by the Technical Expert Panel and patients. For additional details, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in the Hip and Knee Arthroplasty Patient-Reported Outcomes folder at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*. We thank commenters for their recommendations and will consider this feedback during routine measure reevaluation.

After consideration of the public comments we received, we are finalizing the proposal as proposed.

h. Medicare Spending per Beneficiary (MSPB) Hospital Measure (NQF #2158) Beginning With the FY 2024 Payment Determination

For the purpose of continuing to assess hospitals' efficiency and resource use and to meet statutory requirements under section 1886(o)(2)(B)(ii) of the Act, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28529 through 28532) we proposed the adoption of the re-evaluated version of the MSPB Hospital measure in the Hospital IQR Program. We plan to subsequently propose this for the Hospital VBP Program measure set under the Efficiency and Cost Reduction Domain sometime in the future.

(1) Background

In the FY 2012 IPPS/LTCH PPS final rule, we adopted a prior version of the MSPB Hospital measure in both the Hospital IQR Program (76 FR 51618) and the Hospital VBP Program (under the Efficiency and Cost Reduction Domain) (76 FR 51654). The original MSPB Hospital measure was subsequently removed from the Hospital IQR Program beginning with the FY 2020 payment determination, under the proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program (83 FR 41559). The original version of the MSPB Hospital measure that was removed from the Hospital IQR Program was identical to the version that was concurrently, and continues to be used in the Hospital VBP Program. For more information on the removal of the original MSPB Hospital measure from the Hospital IQR Program, please see section VIII.A.4.b of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544). We note that adding the updated MSPB Hospital measure with the refinements outlined previously to the Hospital IQR Program would follow the process associated with adopting new measures into the Hospital VBP Program, as specified under section 1889(o)(2)(C)(i) of the Act, and provide beneficiaries, hospitals, and other stakeholders with an opportunity to familiarize themselves with this updated version of the measure before we propose to replace the original MSPB Hospital measure in the Hospital VBP Program and calculate incentive payment adjustments for eligible hospitals. Given that the proposed updated MSPB Hospital measure is different from the original MSPB Hospital measure currently in use in the Hospital VBP Program, we believe that including the updated MSPB Hospital measure in the Hospital IQR Program will not incur costs that justified the removal of the original MSPB Hospital measure from the Hospital IQR Program in the FY 2019 IPPS/LTCH PPS final rule.

The original MSPB Hospital measure evaluated hospitals' efficiency relative to the efficiency of the national median hospital. Specifically, it assessed the cost to Medicare during an episode of care, which is composed of the period three days prior to an IPPS hospital admission through 30 days after discharge. The measure included Medicare Part A and B payments for services provided to a Medicare beneficiary during an episode. The costs included in this measure were payment standardized to remove sources of variation not directly related to hospitals' care decisions, such as geographic differences in practice expenses. The measure was risk adjusted to account for factors outside of hospitals' influence. The details of the original MSPB Hospital episode construction and measure calculation can be found in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627).

As part of our measure maintenance process (as required in section 8 of the Blueprint for the CMS Measures Management System Version 17.0 available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), we comprehensively re-evaluated the original MSPB Hospital measure in 2020, after it was removed from the Hospital IQR Program beginning with the FY 2020 payment determination period. The re-evaluation was informed by feedback received on this measure through prior public comment periods [944] and the literature. Specifically, regarding the all-cost nature of the measure, some stakeholders raised concerns that an all-cost approach may result in the measure capturing services that are not under the influence of the facilities or practitioners, while others noted that there is a need for all-cost/condition measures such as the MSPB Hospital

[944] We received feedback during the public comment periods of the FY 2012 and FY 2013 IPPS/LTCH PPS proposed rules. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51619 through 51627) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53584 through 53592) for a summary of the comments received.

measure to promote broad incentives for care coordination. Regarding readmissions triggering new episodes, commenters noted that potentially high cost services occurring after an inpatient readmission are not fully captured under the current methodology that does not allow readmissions to initiate new episodes, and that the correlation between the MSPB Hospital measure and the Hospital Readmission Reduction Program's readmission measures is weak. Finally, some commenters suggested potential need for social risk factor (SRF) adjustments.[945] Relatedly, the literature has identified dual enrollment in Medicare and Medicaid as a potentially meaningful SRF to adjust for in the VBP programs.[946]

In the process of evaluating this feedback, the TEP reviewed four main topics to explore as potential changes to the specifications, including:

(1) Narrowing the all-cost approach through service inclusion and exclusion rules;

(2) Including SRFs in the measure's risk adjustment model;

(3) Allowing readmissions to trigger a new episode and include an indicator variable in the risk adjustment model for whether there was an inpatient stay in the 30 days prior to episode start date; and

(4) Changing the measure calculation from the sum of observed costs divided by the sum of expected costs to the mean of observed costs divided by expected costs.

After reviewing the analyses prepared by the measure development contractor and discussed during the February 2020 meeting, the TEP members provided feedback on each of the potential refinements during the process of re-evaluation. In brief, the TEP believed that the current all-cost methodology approach appropriately reflected the broad scope of a hospital's responsibility of care, and that this was needed to promote broad incentive for care coordination. TEP members highlighted the need for further testing around the impact of including SRF variables in the risk adjustment model. The TEP supported the refinement to allow readmissions to trigger new episodes, as they believed it was clinically appropriate to hold the hospital responsible for these costs. The members also agreed that the slight change to the measure calculation would reduce the impact of outliers on the final measure scores. The summary of the TEP's discussions of the MSBP Hospital measure is in the February 2020 Physician Cost Measures and Patient Relationship Codes TEP Summary Report.[947]

Through the re-evaluation process and the feedback that was provided by the TEP, we identified three refinements to the measure which will ensure a more comprehensive and consistent reflection of hospital performance by capturing more episodes and adjusting the measure calculation. First, we refined the measure to include all readmissions to trigger new episodes to account for episodes and costs that are currently not included in the measure but that could be within the hospital's reasonable influence. Second, we added an indicator variable in the risk adjustment model for whether there was an inpatient stay in the 30 days prior to episode start date. And third, we revised the measure to change one step in the measure calculation from the sum of observed costs divided by the sum of expected costs (ratio of sums) to the mean of observed costs divided by expected costs (mean of ratios). Based on our measure development contractor's recommendations, informed by the guidance from the TEP and the additional testing of the potential refinements suggested by the TEP, we believe that these changes will benefit the MSPB Hospital measure's relevance and statistical stability as well as ensure a more comprehensive and consistent reflection of hospital performance by capturing more episodes and adjusting the measure calculation. We describe these changes in a summary of the measure re-evaluation on the CMS QualityNet website posted in July 2020.[948]

We proposed the updated MSPB Hospital measure for the Hospital IQR Program that incorporates the three changes, which are detailed in the subsequent discussion. We note that aside from these three described refinements, all other aspects of the updated measure are the same as compared to the original measure.

[945] FY 2012 IPPS/LTCH PPS final rule (76 FR 51624 through 51625) and FY 2013 IPPS/LTCH PPS final rule (77 FR 53586 through 53587).

[946] Johnston, K.J. & Maddox, K.E.J. (2019). The Role of Social, Cognitive, And Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees.

[947] Physician Cost Measures and Patient Relationship Codes TEP Summary Report. (2020). Available at: *https://www.cms.gov/files/zip/physician-cost-measures-and-patient-relationship-codes-pcmp.zip*.

[948] Medicare Spending Per Beneficiary (MSPB) Measure Methodology. Available at: *https://qualitynet.cms.gov/inpatient/measures/mspb/methodology*.

(a) Update To Allow Readmissions To Trigger New Episodes

First, we refined the measure to allow readmissions to trigger new episodes to account for episodes and costs that are currently not included in the measure but that could be within the hospital's reasonable influence. It is clinically appropriate to hold the hospital responsible for the costs that are associated with the readmissions (that is, from 3 days prior to the readmission through 30 days post-discharge) to encourage care transitions and coordination in improving patient care and reducing unnecessary readmissions. Under the previously adopted measure methodology, the measure only included episodes that are triggered by initial hospital admissions, and inpatient readmissions occurring in the 30-day post-discharge period of an existing episode are excluded from initiating new episodes (76 FR 51620 through 51624). Allowing readmissions to trigger new episodes will increase the number of episodes for which a provider can be scored and align the incentives of the measure during readmissions, by encouraging hospitals to provide cost efficient care and improve care coordination not only during initial hospitalizations, but also during readmissions. This refinement will also ensure that the measure captures potentially high-cost services that would otherwise be excluded.

To illustrate this refinement, take for example a beneficiary who is admitted to an inpatient hospital for a spinal procedure with major complication or comorbidity (MS–DRG 028). This hospital admission triggers an episode (Episode 1), where the episode window starts three days prior to the admission date and ends 30 days after discharge. Episode 1 is attributed to the hospital where the inpatient stay occurs. Fifteen days after being discharged from the hospital, the beneficiary needs to receive additional inpatient hospital care for pneumonia (MS–DRG 194). This readmission occurs within the 30-day post-discharge period of Episode 1 (that is, the episode triggered by the initial hospitalization), and will trigger a new episode (Episode 2). Episode 2's window will start three days prior to this readmission and end 30 days after discharge. Episode 2 will be attributed to the hospital managing this readmission. Under the previous methodology, the readmission would not be calculated under the measure as a new episode because it occurred during the 30-day post-discharge period of Episode 1. However, under the proposed new methodology, the

readmission will trigger a new episode (Episode 2), and the episode will be included in the MSPB rate for the hospital managing the readmission. Episode 2 will include the costs in the post-discharge period of the readmission that would not be previously captured. Additionally, the costs where Episode 1 and Episode 2 overlap will be counted towards each episode. We note that the services being assigned to these episodes will only be counted once per episode. In other words, costs will not be double-counted. The revised measure calculation compares each hospital's observed episode costs to predicted episode costs among their peers for patients with the same observable characteristics, rather than to a pre-defined standard. By comparing hospitals to other hospitals that are all attributed in the same way, we expect this comparison to be fair. This also helps to maintain care coordination incentives of the MSPB Hospital measure.

(b) New Indicator Variable in the Risk Adjustment Model

Additionally, to account for the differences in expected costs for episodes that are triggered by readmissions, the updated methodology includes an indicator variable in the risk adjustment model showing whether there was an inpatient stay in the 30 days prior to episode start date. The previous methodology does not include this indicator variable, given that all episodes with an inpatient stay in the 30 days prior to the episode start date (that is, episodes that are based on a hospital readmission) are excluded from the measure calculation (76 FR 51620 through 51624). Continuing with the example used earlier, given that Episode 2 is based on a hospital readmission and there was an inpatient stay within 30 days prior to its episode start date, the risk adjustor indicator will be turned on for Episode 2. This means that when we calculate predicted spending for Episode 2, the risk adjustment model will take into account the fact that this episode was triggered by a readmission, and not an initial admission. This will ensure that the hospital is not unfairly penalized for providing care to the patient during the episode that could be more high cost due to its readmission status.

An illustration of this refinement that compares the previously adopted methodology where a readmission does not trigger a new episode and the proposed new methodology where a readmission does trigger a new episode, is available in Appendix B of the Measure Information Form (MIF) document available at: *https://qualitynet.cms.gov/files/5f1b3bd12bd4670021abc1b4?filename=MSPB_Hospital_MIF_2020.pdf*.

(c) Updated MSPB Amount Calculation Methodology

The third refinement changes one step in the measure calculation from the sum of observed costs divided by the sum of expected costs (ratio of sums) to the mean of observed costs divided by expected costs (mean of ratios). Under the previously adopted methodology, we calculated the MSPB Amount as follows: ((Sum of Observed Costs//# of Attributed Episodes)/(Sum of Expected Costs/# of Attributed Episodes)) * Average Observed Cost Nationally (76 FR 51626). The revised methodology calculates the MSPB Amount instead as follows: (Sum (Observed Costs/Expected Costs)/# of Attributed Episodes) * Average Observed Cost Nationally. Under this refinement, changing the measure calculation will: (a) Slightly increase measure reliability with minimal score changes; and (b) evenly weight attributed episodes in the final performance score, where previously good or poor performance on more expensive episodes will have more weight in the provider's final score. Specifically, by changing the measure calculation, the impact of outlier episodes on a measure score will be reduced (under the previously adopted calculation methodology, most costly episodes are weighted proportionately, which will make the measure slightly more sensitive to outlier episodes).

Additionally, the updated MSPB Hospital measure will further align with MSPB cost measures in other settings, including the MSPB Clinician measure in MIPS (84 FR 62974 through 62977), and the MSPB-Post Acute Care (PAC) measures, including MSPB–PAC for Inpatient Rehabilitation Facilities (81 FR 52087 through 52095), Long-Term Care Hospitals (81 FR 57199 through 57207), Skilled Nursing Facilities (81 FR 52014 through 52021), and Home Health Agencies (81 FR 76757 through 76765). The updated MSPB Hospital measure will also align with the acute inpatient medical condition episode-based cost measures in MIPS (83 FR 59767 through 59773, 84 FR 62962 through 62968. and 86 FR 65446 through 65453). We note that while the scope of care is different for clinician, hospital, and post-acute care level measures, we believe aligning these measures will help to ensure consistent care coordination incentives between the hospital, post-acute care facility, and the clinician(s) providing care in those settings.

(2) NQF Re-Endorsement

This original MSPB Hospital measure was first endorsed by the NQF in 2013 [949] and then again in 2017.[950] We presented the updated MSPB Hospital measure (NQF ID #2158) with these three refinements to NQF in the Fall 2020 cycle for measure re-endorsement. During the Fall 2020 NQF endorsement cycle, the updated MSPB Hospital measure was reviewed by the Scientific Methods Panel (SMP), Cost and Efficiency Standing Committee, and Consensus Standards Approval Committee (CSAC) during the 11-month endorsement process.[951] The updated measure passed on the reliability and validity criteria when reviewed by the SMP. The Cost and Efficiency Standing Committee reviewed each aspect of the updated measure in detail across three meetings. They also closely reviewed our testing around the impact of social risk factors. Specifically, we had tested whether the inclusion of sex, dual eligibility status, race/ethnicity, the AHRQ SES index, components of the AHRQ SES index, and the Area Deprivation Index could meaningfully be incorporated into the measure, so as not to penalize the hospital for the patients they treat, while also not setting a lower standard of care for hospitals with patients that have social risk factors. Results showed that the inclusion of these social risk factors had a limited and inconsistent effect on measure scores, and some of the variation that was captured by tested covariates was attributable to the hospital in which the episodes were initiated. Therefore, social risk factors continue to not be included in the measure's risk adjustment model. The CSAC approved the Standing Committee's endorsement recommendation unanimously, meaning that the updated MSPB Hospital measure (NQF #2158) was re-endorsed in June 2021 with the three refinements discussed.[952]

[949] The NQF Cost and Resource Use—Phase 3 Final Report is available at: *https://www.qualityforum.org/Publications/2015/02/Cost_and_Resource_Use_-_Phase_3_Final_Report.aspx*, and the 2013 NQF measure evaluation form is available at: *https://www.qualityforum.org/Projects/c-d/Cost_and_Resource_Project/2158.aspx*.

[950] NQF. (2017). Cost and Resource Use 2016–2017 Final Technical Report. Available at: *https://www.qualityforum.org/Publications/2017/08/Cost_and_Resource_Use_2016–2017_Final_Technical_Report.aspx*.

[951] The submission materials, including the testing results, are available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86056&cycleNo=2&cycleYear=2020*.

[952] NQF. (2020). Cost and Efficiency Final Report—Fall 2020 Cycle. Available at: *https://www.qualityforum.org/Publications/2021/09/*

Continued

(3) Measure Applications Partnership Review

Following NQF re-endorsement, the updated measure was included in CMS's ''List of Measures Under Consideration for December 1, 2021.'' [953] The updated MSPB Hospital measure (MUC2021–131) underwent MAP review during the 2021–2022 cycle. On December 15, 2021, the MAP Hospital Workgroup supported the updated measure for rulemaking. On January 19, 2022, the MAP Coordinating Committee upheld the MAP Hospital Workgroup's preliminary recommendation to support the updated measure for rulemaking. More detail on the discussion is available in the MAP's final report.[954]

We proposed the updated MSPB Hospital measure (NQF #2158) for the Hospital IQR Program beginning with the FY 2024 payment determination and for subsequent years. This will allow us to assess hospitals' efficiency and resource use and meet statutory requirements for future adoption in the Hospital VBP Program.[955]

We invited public comment on this proposal.

Comment: Several commenters supported the proposed revisions to the MSPB Hospital measure, and the measure's adoption in the Hospital IQR Program in general. Some commenters expressed specific support for the refinement to allow readmissions to trigger a new episode, with a commenter stating that this refinement would encourage greater care coordination and shared accountability for avoidable readmissions. A commenter supported the refinement to add an indicator in the risk adjustment model for a previous inpatient stay within 30 days of the episode start date. A few commenters were also appreciative that the revised measure was NQF-endorsed prior to its proposal to be included in the Hospital IQR Program.

Response: We appreciate the commenters' support for inclusion of the revised MSPB Hospital measure in the Hospital IQR Program.

Comment: While some commenters supported the proposed revisions to the MSPB Hospital measure, a few commenters urged that we share information on the impact of proposed refinements on the measure. A few commenters requested that we provide example calculations under the revised and original measure versions to illustrate the potential effects of the proposed measure calculation changes and their impact on hospitals. A commenter noted that they would be interested to see how the revised version of the MSPB Hospital measure and the measure scores compare to those of the current version of the measure that is currently used in the Hospital VBP Program. The commenter further noted that they would be interested in how the refinement of the measure calculation would affect Hospital VBP Program scores and outcomes. Finally, a commenter urged that we closely monitor the results for both versions of the measure in the Hospital IQR and Hospital VBP Programs for any unintended consequences, especially during the period of time when the measure specifications are not aligned.

Response: We thank the commenters for their feedback. We note that as part of the NQF endorsement process, we provided statistics on the impacts of the proposed refinements to the measure. For example, Table 3.b of the testing appendix that was submitted to NQF contains an analysis of changes in MSPB Hospital measure scores between the current version of the measure and the version of the measure with proposed refinements implemented. In addition, Table 3.a includes testing results on the MSPB Hospital measure episodes stratified by whether an episode was triggered by an original hospitalization or a readmission. The submission materials that include these testing results are available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86056&cycleNo=2&cycleYear=2020*. Additional information on the impact of the refinements and the TEP's discussion on each refinement is also available in the February 2020 Physician Cost Measures and Patient Relationship Codes TEP Summary Report available at: *https://www.cms.gov/files/zip/physician-cost-measures-and-patient-relationship-codes-pcmp.zip*. In order to evaluate the impact of the refinements on the Hospital VBP Program scores (that is, the Total Performance Scores that are used to adjust hospital payments) and outcomes, the measure would need to be implemented in the Hospital VBP Program, so that hospital performance on the measure can be aggregated with hospital performance on measures in other domains. We will continue monitoring the results for both versions of the measure in each program for any unintended consequences in the future.

Comment: Some commenters expressed concerns that for a period of time, there would be two slightly different versions of the measure used to assess hospital performance in the Hospital IQR and the Hospital VBP Programs, respectively. Commenters noted that this could make it difficult for hospitals to interpret performance results and could lead to additional burden on providers who would need to track two different reporting rates. Some commenters also expressed concerns about publicly reporting two versions of the MSPB Hospital measure, with a commenter requesting clarification on how these measures would be distinguished for the public. Some commenters recommended that we suppress one set of measures from public reporting, but maintain both results in downloadable files. To reduce any confusion caused by having two version of the measures being simultaneously reported publicly, a few commenters recommended only publicly reporting the current measure that is used in Hospital VBP Program, while waiting for at least one year before starting to publicly report the revised version of the measure. Another commenter recommended suppressing the version used in Hospital VBP Program if the revised version is used in the Hospital IQR Program and made publicly available.

Response: We thank the commenters for raising these concerns. As we have previously stated (87 FR 28529), a couple of goals of adopting the revised version of the measure in the Hospital IQR Program is to publicly report it for at least a year in order to meet requirements for potential future use in the Hospital VBP Program (as required by the Hospital VBP Program statute at section 1886(o) of the Act) as well as to provide interested parties with an opportunity to become familiar with the new version of the measure and provide feedback. Therefore, we do not want to delay the public reporting of the measure by one year, as suggested by the commenters. Additionally, by statute, there must be a cost measure in the Hospital VBP Program, which is the MSPB Hospital measure, so we are unable to remove the current version of the measure from Hospital VBP Program, as it is the only cost measure under the Efficiency and Cost Reduction

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Cost_and_Efficiency_Final_Report_-_Fall_2020_Cycle.aspx.

[953] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96464*.

[954] National Quality Forum, (2022) Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care (*https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*).

[955] Sections 1886(o)(2)(B)(ii) and 1886(o)(2)(C)(i) of the Social Security Act (*https://www.ssa.gov/OP_Home/ssact/title18/1886.htm*).

domain and we believe this domain is an essential part of assessing value in addition to quality in the program. We will work to clearly identify the version of the measure when publicly reporting the revised MSPB Hospital measure and help address any potential confusion. The updated version of the measure will be posted with other Hospital IQR Program data on the Compare tool, which displays data in a consumer-focused way. Hospital VBP Program data will continue to be posted to *data.cms.gov* which presents the data as downloadable files and is targeted more towards data analysts and researchers rather than consumers. We also plan to publicly post educational materials and provide support via help desk to respond to stakeholder inquiries.

Comment: Several commenters did not support the measure and expressed concerns that allowing readmissions to trigger a new episode in the revised MSPB Hospital measure could lead to the same costs being attributed to hospitals twice and potentially result in a misleading portrayal of hospital performance. Another commenter expressed concern that a facility would be penalized twice related to readmissions, once through in the Hospital IQR Program based on their performance on the revised MSPB Hospital measure, and again through the Hospital Readmissions Reduction Program.

Response: We thank the commenters for raising these concerns. As previously stated in the proposed rule(87 FR 28530), the refinement allows readmissions to trigger new episodes which would result in some services being assigned to multiple episodes. These services, however, would only be counted once per episode, so the cost of these services would not be counted twice within the same episode. Additionally, the presence of an inpatient admission within 30 days before the start date of an episode based on a readmission is controlled for in the risk adjustment model to account for the additional complexity that readmissions may entail.[956] Further, the inclusion of episodes triggered by readmissions does not necessarily result in a worse measure score for the provider. Such episodes still use the observed over expected cost ratios, where it is possible for the observed cost to be lower than expected cost, if the hospital performed better on the episode than expected. Additionally, we do not agree with the commenter's statement that this refinement would result in hospitals being penalized twice. The revised MSPB Hospital measure, whether used in the Hospital IQR Program or Hospital VBP Program, and the condition- and procedure-specific readmission measures used in the Hospital Readmissions Reduction Program assess readmissions for different purposes (for example, assess hospitals' cost efficiency on readmissions and reduce avoidable readmissions, respectively) to help encourage hospitals to provide higher value care to their patients; thus, it is beneficial to have this alignment. Additionally, allowing readmissions to trigger new MSPB Hospital episodes does not impact a hospital's readmissions rates, given that it merely captures episodes that are based on existing readmissions so that those episodes can be used to assess hospital performance.

Comment: Several commenters did not support the measure, expressing concerns that the reliability and validity of the revised MSPB Hospital measure are low.

Response: We respectfully disagree with the comments that the reliability and validity of the revised MSPB Hospital measure are low. The NQF rated reliability as high when endorsing the measure. The average reliability score of hospitals with at least 25 episodes was 0.92,[957] [958] which far exceeds the standard generally considered as 'high' reliability. The NQF rated validity as moderate when endorsing the measure.[959] [960] As part of the NQF endorsement submission, we undertook three approaches to empirically examine the extent to which the revised MSPB Hospital measure captures what it intends to capture. Firstly, we examined the relationship between risk adjusted episode cost ratios and episodes with and without post-admission events that are known indicators of high cost or intensive care. Secondly, we examined the relationship between a hospital's average expected episode cost and average episode rates of several service use categories, to test whether the risk adjustment model can predict patient need for certain services. Thirdly, we examined the relationship between the revised MSPB Hospital measure and other cost-specific measures, efficiency-related measures, and measures in other Hospital VBP Program domains. For all three types of validity testing, we observed results that were in line with our expectations, demonstrating that the measure is functioning as intended.

Comment: Some commenters raised concerns about the risk adjustment approach for the revised MSPB Hospital measure. Specifically, a few commenters were concerned that the measure does not adjust for social risk factors. A commenter stated that social risk factors should not be considered supplementary to clinical risk factors in risk adjustment models. Additionally, a commenter did not believe that the risk adjustment model's fit with the unadjusted and adjusted R-squared (ranging from 0.11 to 0.67) was sufficiently addressed. Finally, a commenter requested for additional clarification on whether the revised MSPB Hospital measure takes into account patient acuity, impact of patient social drivers of health, supply chain impact, COVID–19 impacts, and short staffing as variables that could impact Medicare spending per beneficiary.

Response: We thank the commenters for their feedback. As noted previously, as part of the NQF endorsement submission we assessed the impact of social drivers of health on the measure, conducting testing based on NQF precedents, as well as supplemented with novel testing and in response to specific stakeholder feedback. The NQF's Scientific Methods Panel carefully reviewed the testing results on the impacts of social risk factors on the measure and our recommendation to continue not including them in the measure's risk adjustment model, and passed the measure on validity criterion. Additionally, as part of normal measure maintenance, we plan to continue to conduct testing and monitoring of the impact of social risk factors on the measure.

Regarding the commenter's note about the measure's low R-squared metrics that were included in the NQF endorsement submission materials, we would like to clarify that R-squared metrics, which are calculated to analyze the proportion of cost variation explained by the risk adjustment model,

[956] Medicare Spending Per Beneficiary (MSPB) Measure Methodology. Available at: *https://qualitynet.cms.gov/inpatient/measures/mspb/methodology.*

[957] The submission materials, including the testing results, are available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86056&cycleNo=2&cycleYear=2020.*

[958] NQF's Cost and Efficiency Final Report with the summary of the Scientific Methods Panel's and Standing Committee's discussion is available here: *https://www.qualityforum.org/Publications/2021/09/Cost_and_Efficiency_Final_Report_-_Fall_2020_Cycle.aspx.*

[959] The submission materials, including the testing results, are available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86056&cycleNo=2&cycleYear=2020.*

[960] NQF's Cost and Efficiency Final Report with the summary of the Scientific Methods Panel's and Standing Committee's discussion is available here: *https://www.qualityforum.org/Publications/2021/09/Cost_and_Efficiency_Final_Report_-_Fall_2020_Cycle.aspx.*

should be interpreted within the context of the measure construction, what it is intended to capture, and its use. A low R-squared is conceptually neither required nor expected for a ''valid'' measure, so some valid measures will have low R-squared metrics, while others will have high R-squared metrics. We also note that extensive testing demonstrates the validity of the risk adjustment models for the revised MSPB Hospital measure, with model discrimination and calibration results demonstrating predictive ability across the full range of episodes, from low to high spending risk. There was no evidence of excessive under- or over-estimation at the extremes of episode risk.

Given that the revised MSPB Hospital measure is calculated using administrative claims data, the measure is unable to directly account for supply chain impacts and short staffing. Regarding the commenter's note on the impact of COVID–19 on the measure, given that the measure uses a risk adjustment model that is run separately for each Major Diagnostic Category (MDC), and COVID–19 diagnoses are mapped to particular Diagnosis-Related Groups (DRGs), the measure would adjust for COVID–19 when risk adjusting by the DRG of the hospitalization. We also observed that COVID–19 hospitalizations are highly concentrated within MDC 4 (*Respiratory System*), which further improves comparability of COVID–19 episodes to non-COVID–19 episodes. We will continue monitoring the effects of COVID–19 on both the current and revised versions of the MSPB Hospital measure, however, because of the ways the measure already accounts for COVID–19 hospitalizations as described, we do not believe any additional adjustments for COVID–19 are needed at this time.

Finally, the measure's risk adjustment methodology accounts for patient case-mix and other factors by adjusting for patient age and severity of illness. Specifically, the risk adjustment methodology includes 12 age categorical variables, 79 hierarchical condition category (HCC) indicators, status indicator variables for whether the beneficiary qualifies for Medicare through disability or age and End-Stage Renal Disease (ESRD), indicators to account for disease interactions, an indicator of whether the beneficiary recently required long-term care, and the Medicare Severity-Diagnosis Related Group (MS–DRG) of the index hospitalization. We believe this provides adequate adjustment for patient acuity.

Comment: A few commenters raised concerns about a lack of alignment between the revised MSPB Hospital measure and relevant quality data, and stated that without this alignment or the incorporation of these data into the revised MSPB Hospital measure, it cannot accurately assess efficiency. The commenters believe that efficiency of care must be a measure of cost of care associated with a specified level of quality of care. They also believe measures should be grounded in current best evidence, should evaluate clinical outcomes concurrently with resource use, and should be interpretable based on outcomes achieved with resources expended. The commenter added that to fully interpret cost measure data, relevant quality data must also be available. The inclusion of cost measures alone could discourage the provision of needed care or innovative treatments to reduce costs. As a result, the commenter encouraged that we investigate alternative frameworks for efficiency measurement to properly align the evaluation of cost and quality.

Response: We thank the commenters for their feedback. For the purposes of the Hospital IQR Program, we determine the quality of care provided by hospitals to their patients by using a variety of measures that include both cost and quality measures, thus ensuring alignment between cost and quality. Specifically, such measures include payment measures (including four condition-specific measures and the revised MSPB Hospital measure being proposed), patient safety, morality outcome, patient experience of care survey, and others. Similarly, in the Hospital VBP Program, the revised MSPB Hospital measure would be used in alignment with several quality measures that span Clinical Outcomes, Person and Community Engagement, and Safety measure domains, so together these measures would facilitate profiling hospital value, from both the cost and quality perspectives. In addition, to ensure that hospitals are able to understand their performance on the revised MSPB Hospital measure and identify areas for improvement, eligible hospitals will receive Hospital-Specific Reports (HSRs) that contain different breakdowns of the hospital's performance on the measure. Providing these files to hospitals would also allow them to provide informed feedback on the measure to the measure developer and CMS.

We also add that the measure itself safeguards against potential care stinting by including the costs of consequences of care. For example, if the attributed hospital attempts to reduce costs by discharging a patient too early, it could result in higher post-acute care costs, re-hospitalization for complications, or emergency department visits soon after the discharge, which would be captured by the measure, resulting in worse performance. Testing submitted as part of the NQF endorsement cycle demonstrated that the measure accurately reflects high-cost adverse outcomes, confirming that the measure can appropriately distinguish that better providers tend to have fewer downstream re-hospitalizations and post-acute care use.[961] Thus, by being able to differentiate between good and poor performance, the measure is able to accurately assess a hospital's efficiency as compared to other hospitals.

Finally, to address a commenter's feedback that the measure should be grounded in current best evidence and practices, we note that prior to being proposed in the FY 2023 IPPS/LTCH PPS proposed rule, the NQF and MAP reviewed the revised MSPB Hospital measure against the measure evaluation criteria, which include importance to measure and report, scientific acceptability of measure properties, feasibility, usability and use, and related/competing measures, to ensure the measure's suitability, and subsequently recommended the measure for endorsement and implementation in the Hospital IQR Program.

Comment: A commenter recommended that CMS delay adopting the revised MSPB Hospital measure in the Hospital IQR Program until the FY 2025 payment determination due the impact that COVID–19 could have on measure calculations.

Response: We appreciate the commenter's concern that the impact of COVID–19 on the healthcare system has been profound. We intend to closely monitor the effect of COVID–19 on the revised MSPB Hospital measure and the Hospital IQR Program. As noted previously, by construction the revised MSPB Hospital measure adjusts for COVID–19 when risk adjusting by the DRG of the hospitalization. Additionally, for the MSPB Hospital measure currently used in the Hospital VBP Program, our analyses using data from the first three quarters of 2021 showed that admission volumes returned to near pre-COVID–19 levels, while cost ratios were not significantly different for episodes with and without COVID–19. Based on the findings

[961] The submission materials, including the testing results, are available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86056&cycleNo=2&cycleYear=2020.*

indicating that COVID–19 had a small impact on the measure in 2021, we did not propose to suppress the measure for the purposes of Hospital VBP Program scoring. We disagree about delaying the implementation of the measure in the Hospital IQR Program as this would prevent stakeholders from familiarizing themselves with the revised version of the measure and would further delay the potential future implementation of the measure in the Hospital VBP Program.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

i. Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure (NQF#1550) Beginning With the FY 2024 Payment Determination

(1) Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53516 through 53521) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50062 through 50063), we adopted the Hospital-Level RSCR Following Elective Primary THA/TKA (hereinafter referred to as the THA/TKA Complication measure) for use in both the Hospital IQR and Hospital VBP Programs, respectively. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49674) for information on the previously adopted measure specifications. Although the measure is still included in the Hospital VBP Program and measure results are still publicly reported, in the FY 2018 IPPS/LTCH PPS final rule (83 FR 41150) we finalized the removal of the measure from the Hospital IQR Program as part of agency-wide efforts to reduce provider burden since the measure was also being reported under the Hospital VBP Program. We, however, believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28532 through 28534), we proposed to adopt the re-evaluated form of the THA/TKA Complication measure with an expanded measure outcome. Since the measure was removed from the Hospital IQR Program, it has been revised to include 26 additional mechanical complication ICD–10 codes which were identified during measure maintenance. The statutory requirements of the Hospital VBP Program are set forth in section 1886(o) of the Social Security Act. As noted at 42 CFR 412.164(b) measures must be publicly reported for one year prior to the beginning of the performance period in the Hospital VBP Program. Therefore, we proposed to adopt this measure into the Hospital IQR Program with the intention to eventually propose the updated measure into the Hospital VBP Program after the required year of public reporting in Hospital IQR Program.

THA and TKA are commonly performed procedures for the Medicare population that improve quality of life. From 2016 to 2019, there were 1,012,190 THA and TKA procedures performed on Medicare fee-for-service (FFS) patients 65 years and older. [962] The number of procedures being performed has steadily increased over the last decade and is projected to reach over four million by 2030. [963] [964] While these procedures can dramatically improve a person's quality of life, they are costly. Based on projections of the annual demand for THA and TKA procedures, researchers estimate that Medicare expenditures on Total Joint Arthroplasty (TJA) could climb from $3.95 billion and $7.42 billion for both primary THA and TKA, respectively, in 2005, [965] to $50 billion by 2030. [966] Complications following elective THA and TKA procedures are rare, but the results can be devastating. Evidence shows that periprosthetic joint infection rates following THA and TKA range from 0.7 percent to 1.6 percent depending upon the population. [967] [968] Reported 30- and 90-day death rates following THA range from 0.4 percent to 0.7 percent. [969] Rates for pulmonary embolism following THA range from 0.5 percent to 1.22 percent [970] and range from 0.5 percent to 0.9 percent [971] following TKA. Rates for wound infection in Medicare population-based studies vary between 0.21 percent and 1.0 percent. [972] Rates for sepsis/septicemia range from 0.09 percent during the index admission to 0.3 percent 90 days following discharge for primary TKA. Rates for bleeding and hematoma following TKA range from 0.94 percent to 1.7 percent.[973]

The updated THA/TKA Complication measure was listed in the publicly available document entitled ''List of Measures Under Consideration for December 1, 2021'' [974] (MUC List) with identification number MUC2021–118. The MAP reviewed the updated measure and voted to conditionally support the measure for rulemaking for use in the Hospital IQR Program pending NQF review and endorsement of the measure update. The MAP Rural Health Advisory Group reviewed this updated measure on December 8, 2021 and voted to majority support the measure given that there would be no undue consequences for rural hospitals.[975]

The NQF re-endorsed the original measure in July of 2021; and we intend to submit the updated measure to NQF for endorsement in Fall 2024.[976] We note that section 1866(b)(3)(B)(viii)(IX)(aa) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this

[962] Triche, E., J.N. Grady, and J.e.a. Debuhr, Procedure Specific Complication Measure Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 9.0). 2020.

[963] Kurtz, S., et al., Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am, 2007. 89(4): p. 780–5.

[964] Kurtz, S.M., et al., Impact of the economic downturn on total joint replacement demand in the United States: updated projections to 2021. J Bone Joint Surg Am, 2014. 96(8): p. 624–30.

[965] Kurtz, S.M., et al., Future clinical and economic impact of revision total hip and knee arthroplasty. J Bone Joint Surg Am, 2007. 89 Suppl 3: p. 144–51.

[966] Wilson, N.A., et al., Hip and knee implants: current trends and policy considerations. Health Aff (Millwood), 2008. 27(6): p. 1587–98.

[967] Kurtz S, Ong K, Lau E, Bozic K, Berry D, Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010; 468:5.

[968] Bozic KJ, Grosso LM, Lin Z, et al. Variation in hospital-level risk-standardized complication rates following elective primary total hip and knee arthroplasty. J Bone Joint Surg Am. 2014;96(8):640-647. doi:10.2106/JBJS.L.01639.

[969] Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371.

[970] Arshi A, Leong NL, Wang C, Buser Z, Wang JC, SooHoo NF. Outpatient total hip arthroplasty in the United States: A population-based comparative analysis of complication rates. J Am Acad Orthop Surg. 2019;27(2):61–7.

[971] Khatod M, Inacio M, Paxton EW, et al. Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812–819.

[972] Browne J, Cook C, Hofmann A, Bolognesi M. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. Mar 2010;17(2):152–156.

[973] Huddleston JI, Maloney WJ, Wang Y, Verzier N, Hunt DR, Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1):95–100.

[974] *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.*

[975] *https://www.qualityforum.org/Publications/2022/03/MAP_2021–2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC–LTC.aspx.*

[976] National Quality Forum. Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) Measure Specifications. 2021. *https://www.qualityforum.org/QPS/1550.*

contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

(2) Overview of Measure

The original THA/TKA Complication measure (NQF # 1550) was previously removed from the Hospital IQR Program, but is currently implemented in the Hospital VBP Program (79 FR 50062 through 50063). Adopting the newly refined version of this measure into the Hospital IQR Program will expand the measure outcome to include 26 additional mechanical complication ICD–10 codes. We note that aside from the additional ICD–10 codes, measure specifications align with the version of the measure currently in use in the Hospital VBP Program.

(3) Data Sources

The updated THA/TKA Complication measure uses index admission diagnoses and in-hospital comorbidity data from Medicare Part A claims. Additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment status is obtained from the Medicare Enrollment Database which contains beneficiary demographic, benefit/coverage, and vital status information. We proposed to use claims data with admission dates beginning from April 1, 2019–March 31, 2022 (excluding data from the period covered by the ECE granted by CMS related to the COVID–19 Public Health Emergency (PHE)) that is associated with the FY 2024 payment determination. As a claims-based measure, hospitals will not be required to submit additional data for calculating the measure.

(4) Outcome

The outcome for the updated THA/TKA Complication measure is any complication occurring during the index admission (not coded as present on admission (POA)) to 90 days post-date of the index admission. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a ''yes.''

The updated measure includes the following 26 additional clinically vetted mechanical complication ICD–10 codes:

- M96.65 Fracture of pelvis following insertion of orthopedic implant, joint prosthesis, or bone plate;
- M96.661 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg;
- M96.662 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg;
- M96.669 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg;
- M96.671 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg;
- M96.672 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg;
- M96.679 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg;
- M97.01XA Periprosthetic fracture around internal prosthetic right hip joint, initial encounter;
- M97.01XD Periprosthetic fracture around internal prosthetic right hip joint, subsequent encounter;
- M97.01XS Periprosthetic fracture around internal prosthetic right hip joint, sequela;
- M97.02XA Periprosthetic fracture around internal prosthetic left hip joint, initial encounter;
- M97.02XD Periprosthetic fracture around internal prosthetic left hip joint, subsequent encounter;
- M97.02XS Periprosthetic fracture around internal prosthetic left hip joint, sequela;
- M97.11XA Periprosthetic fracture around internal prosthetic right knee joint, initial encounter;
- M97.11XD Periprosthetic fracture around internal prosthetic right knee joint, subsequent encounter;
- M97.11XS Periprosthetic fracture around internal prosthetic right knee joint, sequela;
- M97.12XA Periprosthetic fracture around internal prosthetic left knee joint, initial encounter;
- M97.12XD Periprosthetic fracture around internal prosthetic left knee joint, subsequent encounter;
- M97.12XS Periprosthetic fracture around internal prosthetic left knee joint, sequela;
- M97.8XXA Periprosthetic fracture around other internal prosthetic joint, initial encounter;
- M97.8XXD Periprosthetic fracture around other internal prosthetic joint, subsequent encounter;
- M97.8XXS Periprosthetic fracture around other internal prosthetic joint, sequela;
- M97.9XXA Periprosthetic fracture around unspecified internal prosthetic joint, initial encounter;
- M97.9XXD Periprosthetic fracture around unspecified internal prosthetic joint, subsequent encounter;
- M97.9XXS Periprosthetic fracture around unspecified internal prosthetic joint, sequela; and
- M96.69 Fracture of other bone following insertion of orthopedic implant, joint prosthesis, or bone plate.

During routine measure maintenance, our analyses showed the addition of these clinically relevant codes contributed to an increase in the THA/TKA national observed complication rate. Findings demonstrated an increase of approximately 0.5 percent (from 2.42 percent to 2.93 percent) in the THA/TKA national observed complication rate when evaluated for the FY 2021 performance period (April 1, 2016 through March 30, 2019). These findings suggest that the expanded outcome will allow the updated THA/TKA Complication measure to capture a more complete outcome.

The updated THA/TKA Complication measure as with the version of measure currently implemented in the Hospital VBP Program (86 FR 45279 through 45281), excludes admissions with a principal or secondary COVID–19 diagnosis, POA, from the measure outcome, as outcomes for patients with COVID–19 who are receiving THA/TKA surgery may differ from patients without COVID–19. The four medical complication outcomes that this applies to are:

(1) Acute myocardial infarction (AMI) during a subsequent inpatient admission that occurs within seven days from the start of the index admission; (2) pneumonia or other acute respiratory complication during a subsequent inpatient admission that occurs within seven days from the start of the index admission, (3) sepsis/septicemia/shock during a subsequent inpatient

admission that occurs within seven days from the start of the index admission, and (4) pulmonary embolism during the index admission or a subsequent inpatient admission within 30 days from the start of the index admission. In these cases, readmissions with a principal or secondary diagnosis POA of COVID–19 (U07.1) will be removed from the numerator.

We refer readers to the Hip and Knee Arthroplasty Complications (ZIP) folder on the *CMS.gov* Measure Methodology website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology* for measure specification details on this newly restructured measure.

(5) Cohort

The updated THA/TKA Complication measure continues to include Medicare FFS beneficiaries, aged 65 years or older, having a qualifying elective primary THA or TKA procedure during the index admission. Beneficiaries must be enrolled in Medicare FFS Part A and Part B for the 12 months prior to the date of admission and enrolled in Part A during the index admission. We also note that the updated THA/TKA Complication measure excludes admissions with a principal or secondary COVID–19 diagnosis, POA, from the measure cohort.

(6) Risk Adjustment

The updated THA/TKA Complication measure is risk adjusted using clinically relevant risk variables identified from inpatient and outpatient claims in the 12 months prior to the procedure. We will also include a covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission.

(7) Measure Calculation

The updated THA/TKA Complication measure will be calculated using a hospital risk-standardized complication rate by producing a ratio of the number of ''predicted'' complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of ''expected'' complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national observed complication rate. For each hospital, the numerator of the ratio is the number of complications within the specified time period (up to 90 days) predicted on the basis of the hospital's performance with its observed case mix, and the denominator is the number of complications expected based on the nation's performance with that hospital's case mix. This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses. It conceptually allows for a comparison of a particular hospital's performance given its case mix to an average hospital's performance with the same case mix.

We proposed to adopt the newly restructured version of the THA/TKA Complication measure beginning with admission dates from April 1, 2019–March 31, 2022 (excluding data from the period covered by the ECE granted by CMS related to the COVID–19 Public Health Emergency (PHE)) affecting the FY 2024 payment determination.

(8) Public Reporting

We will also publicly report the updated THA/TKA Complication measure on the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*, or its successor website, beginning in 2023.

We invited public comment on this proposal.

Comment: Many commenters expressed their support for the proposed adoption into the Hospital IQR Program of the updated THA/TKA Complication measure beginning with the FY 2024 payment determination. A commenter noted that they believe the additional complications codes are clinically appropriate to be paired with arthroplasty and will improve the measure's accuracy. A few commenters noted that they believe measuring and reporting risk-standardized complications rates will inform health care providers about opportunities to improve care, strengthen incentives for quality improvement, and promote improvements in the quality of care received by patients and the outcomes they experience. A few commenters reiterated that they believe this measure will provide patients with beneficial information that could guide their choices regarding where they seek care for these procedures, increase transparency for consumers and that it has the potential to lower health care costs by decreasing the likelihood of costly readmissions associated with these complications.

Response: We thank the commenters for their support.

Comment: A few commenters did not support the proposed adoption of the updated THA/TKA Complication measure. A commenter expressed concern that, because they believe that the majority of these procedures take place in outpatient settings, hospitals subject to this measure will be caring for the sickest patients and therefore subject to improper penalties. A commenter did not support the proposed adoption of the updated the THA/TKA Complication measure because they did not believe the updated measure accurately reflects hospital performance. Specifically, they expressed concern that the ICD–10 codes proposed to be included reflect falls and fractures since THA/TKA patients are at a greater risk for falls regardless of the level of care provided at the hospital. A commenter recommended that using the ratio of observed to expected would be an easier concept to understand than the currently used ratio of predicted to expected.

Response: We thank the commenters for their feedback and acknowledge their concerns. We are monitoring the shifts of THA/TKA from the inpatient to outpatient setting as well as the potential impacts on this inpatient only measure. The proposed updated THA/TKA Complication measure is case mix adjusted for patient comorbidities and is a relative performance measure for hospitals performing these elective THA/TKA procedures.[977] As such, we believe that this measure accurately reflects hospital performance even if patients receiving these procedures in the inpatient setting tend to be sicker, on average, than those treated in an outpatient setting.

We believe this updated measure provides an accurate representation of hospital performance. As noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28532 through 28534), during routine measure maintenance, our internal analyses showed the addition of these clinically relevant codes contributed to an increase in the THA/TKA national observed complication rate. Findings demonstrated an increase of approximately 0.5 percent (from 2.42 percent to 2.93 percent) in the THA/TKA national observed complication rate when evaluated for the FY 2021 performance period (April 1, 2016 through March 30, 2019). These findings suggest that the expanded outcome will allow the updated THA/TKA Complication measure to capture a more complete assessment of complications. We note while conducting these analyses, orthopedic surgeons and clinical coding experts vetted the additional 26 mechanical complication ICD–10 codes and agreed they should be included. Thus, these additions are

[977] For more detailed measure specifications, we refer readers to the ''2022 Procedure-Specific Complication Measure Updates and Specifications: THA/TKA'' at the *CMS.gov* QualityNet website at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology*.

directly responsive to input from stakeholders, including hospitals.

Lastly, we thank the commenter for their recommendation related to the reporting ratio. We reiterate that, as proposed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28532 through 28534), the proposed updated THA/TKA Complication measure is calculated using a hospital risk-standardized complication rate by producing a ratio of the number of ''predicted'' complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of ''expected'' complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national observed complication rate. For each hospital, the numerator of the ratio is the number of complications within the specified time period (up to 90 days) predicted on the basis of the hospital's performance with its observed case mix, and the denominator is the number of complications expected based on the nation's performance with that hospital's case mix.[978] This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses, and it conceptually allows for a comparison of a particular hospital's performance given its case mix to an average hospital's performance with the same case mix. Further details on the predicted/expected calculation approach are provided within the THA/TKA Complication Measure Methodology Report and other publicly available resources on our QualityNet website, available at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology*.

Comment: A few commenters expressed concern that the required data collection will be burdensome to hospitals.

Response: We respectfully disagree that the proposed updated THA/TKA Complication measure with the additional 26 complication codes will cause significant data collection burden. Hospitals will not be required to submit additional data for calculating the measure as it is a claims-based measure. As stated in the in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28532 through 28534), the proposed updated THA/TKA Complication measure uses index admission diagnoses and in-hospital comorbidity data from Medicare Part A claims. Additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment status is obtained from the Medicare Enrollment Database which contains beneficiary demographic, benefit/coverage, and vital status information.[979]

Comment: A few commenters expressed concern that the proposed updates to the THA/TKA Complication measure would result in two similar, but not identical, measures in the Hospital IQR Program and the Hospital VBP Program. The commenters believe that public reporting of both measures, which could yield different results, has the potential to be misleading or confusing for providers and patients. A commenter requested clarification on how the versions of the measure will be distinguished in public reporting and which version of the measure will be in use for the Overall Hospital Quality Star Ratings.

Response: We acknowledge the commenters' concerns that two slightly different versions of the measure would be in use in the Hospital IQR and Hospital VBP Programs simultaneously. However, the statutory requirements of the Hospital VBP Program, as set forth in section 1886(o) of the Act and at 42 CFR 412.164(b), state that measures must be publicly reported for one year prior to the beginning of the performance period in the Hospital VBP Program. Therefore, we proposed to adopt this updated version of the THA/TKA Complication measure into the Hospital IQR Program with the intention to consider proposing the updated measure for use in the Hospital VBP Program in the future. As proposed in the FY 2023 IPPS/LTCH PPS proposed rule, the proposed updated THA/TKA Complication measure would be publicly reported on the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*, or its successor website, beginning in 2023 (87 FR 28532 through 28534). Overall Hospital Quality Star Ratings utilize the publicly reported version of the measure on the Compare tool, as finalized in the CY 2021 OPPS/ASC final rule (85 FR 86202). That is, those ratings would use the proposed updated THA/TKA Complication measure with the additional 26 complication codes once it is publicly reported beginning in 2023. Results for the THA/TKA Complication measure currently implemented in the Hospital VBP Program will continue to be available according to program policies (for example, on the Provider Data Catalog) as noted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50062 through 50063).

Comment: A commenter expressed interest in obtaining detailed information about all relevant complications, including the 26 newly added complications, so they can prepare for potential implementation of the new measure.

Response: We thank the commenter for their interest in obtaining the detailed information on the newly added mechanical complication ICD–10 codes. We refer the commenter to the measure specifications as proposed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28532 through 28534) and ICD–10 resources provided publicly here: *https://www.cms.gov/medicare/icd-10/2023-icd-10-pcs*. The annual Procedure-Specific Complication Measure Updates and Specifications Report will be posted during the 2023 spring preview period and will contain any further details related to the added codes. This is expected to be available on our QualityNet website at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology*.

Comment: A commenter was concerned by the lack of inclusion of social risk factors in the measure.

Response: We appreciate commenter's feedback. We are committed to measuring and improving health equity and addressing social risk factors in quality measurement. During the last NQF endorsement maintenance submission for the original THA/TKA Complication measure prior to 2022, comprehensive testing was completed which included an assessment of the impact of social risk as captured by dual eligibility and the AHRQ SES Index.[980] The AHRQ SES Index score considers aspects of socioeconomic status and is computed using U.S. census data, and considers factors including median household income, percentage of persons below the Federal poverty line, unemployment, education, property value, and percentage of persons in crowded households at the 9-digit zip code level.[981] We found wide variation

[978] For more detailed measure specifications, we refer readers to the ''2022 Procedure-Specific Complication Measure Updates and Specifications: THA/TKA'' at the *CMS.gov* QualityNet website at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology*.

[979] For more detailed measure specifications, we refer readers to the ''2022 Procedure-Specific Complication Measure Updates and Specifications: THA/TKA'' at the *CMS.gov* QualityNet website at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology*.

[981] Bonito A, Bann C, Eicheldinger C, Carpenter L. Creation of new race-ethnicity codes and socioeconomic status (SES) indicators for Medicare beneficiaries. Final Report, Sub-Task. 2008;2.

in the prevalence of the two social risk factors we examined, with a large proportion of hospitals treating zero patients with these risk factors. We also found that both had some association with complication risk. However, adjustment for these factors did not have a material impact on hospital RSCRs.[982] Our decisions about which risk factors should be included in each measure's risk adjustment model are based on whether inclusion of such variables is likely to make the measures more successful at illuminating quality differences and motivating quality improvement. Given these empiric findings and program considerations, we chose not to include these two social risk factors in the final risk model. In presenting these results and interpretation, the NQF re-endorsed the original measure (NQF #1550) in June of 2021 without adjustment for patient-level social risk factors.[983] We acknowledge the importance of balancing these competing considerations and we plan to continue to reevaluate this risk adjustment model and available risk factors on an ongoing basis, with the goal of producing the most accurate and fair risk adjustment models for assessing provider performance. Further details related to social risk testing for this measure can be found from downloading the measure specifications from NQF's Surgery Fall Cycle 2020 project here: *https://nqfappservicesstorage.blob.core.windows.net/proddocs/22/Fall/2020/measures/1550/shared/1550.zip*.

Comment: A few commenters encouraged CMS to seek NQF endorsement of this measure.

Response: We thank the commenters for their feedback. The NQF re-endorsed the original measure (NQF #1550) in June of 2021;[984] and we intend to submit the updated measure to the NQF for endorsement maintenance in Fall 2024.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

6. Refinements to Current Measures in the Hospital IQR Program Measure Set

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28534), we proposed refinements to two measures currently in the Hospital IQR Program measure set—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA and/or TKA and Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We provide more details on our proposals in the subsequent discussion.

a. Refinement of the Hospital-Level, Risk-Standardized Payment Associated With an Episode of Care for Primary Elective Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure (NQF #3474) Beginning With the FY 2024 Payment Determination and for Subsequent Years

(1) Background

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28534 through 28536), we proposed a refinement to the Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA and/or TKA Measure (NQF #3474) (hereinafter referred to as the THA/TKA Payment measure), which expands the measure outcome to include 26 clinically vetted mechanism complication ICD–10 codes, for the FY 2024 payment determination and subsequent years. For the purposes of describing the refinement of this measure, we note that the ''outcome'' is defined as hospital-level, risk-standardized payment associated with a 90-day episode-of-care for primary elective THA and/or TKA.

The THA/TKA Payment measure was first adopted into the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49680) for the FY 2018 payment determination and subsequent years. Prior to adopting the measure, the MAP conditionally supported it on December 10, 2014, pending a timely review by the NQF Cost and Resource Use Standing Committee.[985] The MAP recommended harmonizing and determining the most parsimonious approach to measure the costs of hip and knee replacements to minimize the burden and confusion of competing methodologies.[986] The original measure was initially NQF endorsed in June 2019 and will be submitted for the first re-endorsement in Fall 2022.[987]

The proposed refined measure was included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2021'' [988] (MUC List) with identification number MUC2021–120. The refined measure was reviewed by the MAP and conditionally supported for rulemaking pending NQF review and endorsement of the measure update.[989]

As noted earlier we intend to submit the revised measure for the first NQF re-endorsement in the Fall of 2022. We note that section 1866(b)(3)(B)(viii)(IX)(aa) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

(2) Overview of Measure

The proposed measure refinement will expand the measure outcome to include 26 mechanical complication ICD–10 codes to the outcome. This refinement is in alignment with the refinement of the updated THA/TKA Complication measure in section IX.E.5.i. of this final rule. The data sources, cohort, inclusion and exclusion criteria, and risk adjustment remain substantively unchanged. We proposed this measure refinement for the FY 2024 payment determination and subsequent years, reflecting data collected beginning from April 1, 2019 through March 31, 2022 admissions (excluding data from the period covered by the ECE

[982] National Quality Forum. Surgery Fall Cycle 2020. Measure Testing (subcriteria 2a2, 2b1–2b6) Document. November 3, 2020. Available at: *https://nqfappservicesstorage.blob.core.windows.net/proddocs/22/Fall/2020/measures/1550/shared/1550.zip*.

[983] National Quality Forum. Consensus Standards Approval Committee—Measure Evaluation Web Meeting, June 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95862*.

[984] National Quality Forum. Consensus Standards Approval Committee—Measure Evaluation Web Meeting, June 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95862*.

[985] *https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*.

[986] *https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*.

[987] *https://www.qualityforum.org/QPS/QPSTool.aspx*.

[988] *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

granted by CMS related to the COVID–19 PHE).

(3) Data Sources

We did not propose any changes to the data sources for the THA/TKA Payment measure. The measure uses Part A and Part B Medicare administrative claims data that contain payments for Medicare FFS beneficiaries who were hospitalized and underwent an elective THA/TKA. This measure uses three years of data.

(4) Outcome

The primary outcome of this measure is the hospital-level risk-standardized payment for an elective primary THA/TKA episode-of-care. This measure captures payments for Medicare FFS patients across multiple care settings, services, and supplies (inpatient, outpatient, skilled nursing facility, home health, hospice, physician/clinical laboratory/ambulance services, and durable medical equipment, prosthetics/orthotics, and supplies). This measure includes patient copayments as well as payments from coinsurance.

This measure uses the index admission for an elective primary THA/TKA to 90 days postadmission. The measurement includes all payments for the first 30 days after admission and only certain payments based on a pre-defined set of care settings and services for days 31–90. Payments in the 31–90-day window include readmissions for complications as defined in the THA/TKA Complication measure (Mechanical Complications and Periprosthetic Joint Infection/Wound Infection and Other Wound Complications) (see section IX.E.5.i. of this final rule for discussion on this measure), therefore, the expansion of the definition of mechanical complications impacts this measure as well.

As we did not propose any changes besides the addition of the 26 mechanical complication codes, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49674) for information on the previously adopted measure specifications. We refer readers to Hip and Knee Arthroplasty Payment (ZIP) folder on the CMS.gov Methodology website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology* for updated specifications on this measure.

The proposed additional 26 mechanical complication ICD–10 codes are the following:

- M96.65 Fracture of pelvis following insertion of orthopedic implant, joint prosthesis, or bone plate;
- M96.661 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg;
- M96.662 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg;
- M96.669 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg;
- M96.671 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg;
- M96.672 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg;
- M96.679 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg;
- M97.01XA Periprosthetic fracture around internal prosthetic right hip joint, initial encounter;
- M97.01XD Periprosthetic fracture around internal prosthetic right hip joint, subsequent encounter;
- M97.01XS Periprosthetic fracture around internal prosthetic right hip joint, sequela;
- M97.02XA Periprosthetic fracture around internal prosthetic left hip joint, initial encounter;
- M97.02XD Periprosthetic fracture around internal prosthetic left hip joint, subsequent encounter;
- M97.02XS Periprosthetic fracture around internal prosthetic left hip joint, sequela;
- M97.11XA Periprosthetic fracture around internal prosthetic right knee joint, initial encounter;
- M97.11XD Periprosthetic fracture around internal prosthetic right knee joint, subsequent encounter;
- M97.11XS Periprosthetic fracture around internal prosthetic right knee joint, sequela;
- M97.12XA Periprosthetic fracture around internal prosthetic left knee joint, initial encounter;
- M97.12XD Periprosthetic fracture around internal prosthetic left knee joint, subsequent encounter;
- M97.12XS Periprosthetic fracture around internal prosthetic left knee joint, sequela;
- M97.8XXA Periprosthetic fracture around other internal prosthetic joint, initial encounter;
- M97.8XXD Periprosthetic fracture around other internal prosthetic joint, subsequent encounter;
- M97.8XXS Periprosthetic fracture around other internal prosthetic joint, sequela;
- M97.9XXA Periprosthetic fracture around unspecified internal prosthetic joint, initial encounter;
- M97.9XXD Periprosthetic fracture around unspecified internal prosthetic joint, subsequent encounter;
- M97.9XXS Periprosthetic fracture around unspecified internal prosthetic joint, sequela; and
- M96.69 Fracture of other bone following insertion of orthopedic implant, joint prosthesis, or bone plate.

We proposed the addition of these codes as proposed refinements to the THA/TKA Payment measure in response to recent analyses during routine measure maintenance showing that the addition of these codes will increase the national observed complication rate within the proposed THA/TKA Complication measure (NQF #1550) discussed earlier in this final rule. This demonstrates that the exclusion of these codes could result in missed complications. A number of clinicians in the field of orthopedics vetted the proposed addition of the new ICD–10 codes to identify the complications of care. As described in section IX.E.5.i. of the preamble of this final rule, we anticipate the inclusion of these additional complication codes will increase the national observed complication rate and therefore may impact payments. Payments in the 31–90-day window are included readmissions for complications as defined in the proposed THA/TKA Complication measure (Mechanical Complications and Periprosthetic Joint Infection/Wound Infection and Other Wound Complications), therefore, the expansion of the definition of mechanical complications impacts the THA/TKA Payment measure as well. Since the payment measure uses these codes for payment included in the post-30-day window, we also anticipate an increase in total payments.

These refinements to the measure will be effective for admissions from April 1, 2019 through March 31, 2022 (excluding data from the period covered by the ECE granted by CMS related to the COVID–19 PHE) and impacting the FY 2024 payment determination and subsequent years.

We invited public comment on this proposal.

Comment: Several commenters expressed their support for adoption of refinements to the THA/TKA Payment measure beginning with the FY 2024 payment determination.

Response: We thank the commenters for their support.

Comment: A few commenters recommended we update the testing and achieve endorsement of the proposed refinements from NQF before implementation in the Hospital IQR Program. They additionally recommended we consider delaying measure adoption until NQF endorsement is achieved, if unable to be endorsed prior to the proposed implementation timeline. A commenter expressed that they do believe the refined measure to be an improvement over the current version, and while they agreed that it would capture complications being missed by the current measure version, they noted a concern about overlap between this episode payment measure and the MSPB Hospital measure that we are also proposing to adopt into to the Hospital IQR Program beginning with the FY 2024 payment determination.

Response: We thank the commenters for their feedback. As noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28534 through 28536), we intend to submit the revised measure for the first NQF re-endorsement cycle in the Fall of 2022. Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures on this topic, and, therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

We acknowledge the commenters concerns about overlap between the episode payment measure and the revised MSPB Hospital measure discussed in section IX.E.5.h. of the preamble of this final rule. Although the revised MSPB Hospital and THA/TKA Payment measures are aligned in how the outcome is determined by using the same claim standardization process, the revised MSBP Hospital measure cohort includes most, if not all inpatient admissions at a hospital (that is, it is broader) while the cohort of the THA/TKA Payment measure is more narrow and aligns with the THA/TKA Complication measure. The THA/TKA Payment measure was developed to be viewed in combination with the THA/TKA Complication measure as an indicator of value of care. Therefore, the revised MSPB Hospital and THA/TKA Payment measures serve different purposes.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

b. Refinement of the Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) Measure (NQF #2881) Beginning With the FY 2024 Payment Determination and for Subsequent Years

(1) Background

The EDAC After Hospitalization for AMI (hereinafter referred to as AMI EDAC) measure was initially adopted in the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS final rule (FR 80 49660 through 49690) beginning with the FY 2018 payment determination. The measure is intended to capture the quality-of-care transitions provided to discharged patients hospitalized with AMI by collectively measuring a set of adverse acute care outcomes that can occur post-discharge: (1) ED visits, (2) observation stays, and (3) unplanned readmissions at any time during the 30 days post-discharge. Safely transitioning patients from hospital to home requires a complex series of tasks including timely and effective communication between providers, prevention of and response to complications, patient education about post-discharge care and self-management, timely follow-up, and more. Suboptimal transitions contribute to a variety of adverse events post-discharge, including ED evaluation, need for observation, and readmission. Within the Hospital IQR Program's measure set, the AMI EDAC measure illuminates post-discharge outcomes that are important to patients, better informs consumers about care quality, and incentivizes improvement in transitional care.

(2) Overview of Measure

We proposed to refine this measure by increasing the minimum case count for reporting. The NQF Scientific Methods Panel Committee and stakeholder feedback indicated that the measure's reliability was not adequate. Therefore, we proposed to increase the reporting threshold to 50 cases in an effort to balance the need to include as many hospitals as possible while maintaining acceptable measure reliability.[990] The remainder of the AMI EDAC measure specifications, including the data sources, outcome, cohort, exclusion criteria, risk adjustment approach, and measure calculation will remain unchanged as compared to what is currently adopted in the Hospital IQR Program.

For more detailed measure specifications, we refer readers to the ''2017 Condition-Specific Measures Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Excess Days in Acute Care Measures: Acute Myocardial Infarction—Version 2.0'' available in the AMI, HF Excess Days in Acute Care folder on the *CMS.gov* Measure Methodology website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology* and the *CMS.gov* QualityNet website at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology*.

(3) Update to Minimum Case Count

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28536), we proposed a refinement to the currently adopted version of the AMI EDAC measure to increase the minimum case count of 25 to a minimum case count of 50 during the measurement period. The increase to the minimum case count will improve the measure's reliability. Based on internal analyses using the reporting period July 1, 2016 through June 30, 2019, the split-sample intraclass correlation (ICC) with Spearman Brown Adjustment increased when we increased the minimum case count from .384 with 25 admissions to .402 with 50 admissions. Based on our analysis, the mean performance rate for all hospitals was 3.6 excess days per 100 discharges, with a standard deviation of 26.3. For hospitals with at least 50 admissions in the same performance period, the mean performance rate was 6.9 per 100 discharges, with a standard deviation of 22. Additionally, 1,805 hospitals of 4,074 hospitals (or 44.3 percent) meet the minimum case count of 50 admissions for the same performance period.

Based on this improvement in reliability, we proposed to increase the AMI EDAC measure's minimum case count reporting threshold from 25 to 50 beginning with the FY 2024 payment determination using the reporting period July 1, 2019 through June 30, 2022 (excluding data from the period covered by the ECE granted by CMS related to the COVID–19 PHE), for which public display of the measure results will occur as part of a 2023 Compare website refresh (or as soon as operationally feasible thereafter), and

[990] National Quality Forum. Scientific Methods Panel: Spring 2021 Measure Evaluation Meeting Transcript. March 30, 2021. *https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Docs/Transcript_03302021.aspx.*

for subsequent years. Hospitals with fewer than 50 cases for the AMI EDAC measure will continue to receive confidential feedback reports containing measure results to understand their performance. Public reporting of measure results on the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*, or its successor website, will only occur for hospitals meeting the 50 minimum cases required for reporting. Hospitals will not need to submit additional data as the AMI EDAC measure is calculated using administrative claims submitted to CMS for payment purposes.

We invited public comment on this proposal.

Comment: Several commenters expressed their support for the proposed refinements to the AMI EDAC measure beginning with the FY 2024 payment determination. A few commenters noted that they believe increasing the minimum denominator for the AMI EDAC measure from 25 to 50 cases improves measure reliability.

Response: We thank the commenters for their support of our proposal to increase the AMI EDAC measure's minimum case count reporting threshold from 25 to 50 cases.

Comment: A few commenters recommended that the AMI EDAC measure be removed from the Hospital IQR Program. A commenter stated they do not believe the measure adds value to the Hospital IQR Program. Other commenters expressed concerns with the measure outcome being a combination of readmissions, observation stays, and ED visits into a single category, stating their belief that each of these settings reflect widely different approaches to patient-centered care and cannot be meaningfully interpreted from a single number of days. Commenters added that they believe CMS added the AMI EDAC measure with the assumption that the then-new readmission measures would increase use of observation stays and ED visits and stated that evidence to support that assumption is not available.

Response: We thank the commenters for their input but we respectfully disagree that the measure does not add value to the Hospital IQR Program or that it should be removed. We believe the measure adds value to the Hospital IQR Program because the measure illuminates additional post-discharge outcomes that are important to patients beyond readmissions only, better informs consumers about care quality, and incentivizes improvement in transitional care. Regarding the commenters' concern about combining the count of days for readmissions, observation stays or ED visits, we believe this single count can be meaningfully interpreted because, from a patient perspective, it is the count of total days that is most meaningful and representative of the disruption, cost, or risk. This measure is meant to provide patients with a complete picture of potential post-discharge acute care use. For this reason, the AMI EDAC measure's outcome is expressed in days, and we combine day counts for each type of event and do not publicly report rates of each type of event. Further information on the public reporting of the measure can be accessed here: *https://data.cms.gov/provider-data/topics/hospitals/unplanned-hospital-visits/*. Regarding the commenters' concern related to different approaches to patient centered care, we note that the measure developer's discussions with patients and the TEP, as well as published literature, indicate that acute care utilization after discharge (that is, return to the ED, observation stay, and readmission), for any reason, is disruptive to patients and caregivers, costly to the healthcare system, and puts patients at additional risk of hospital-acquired infections and complications. We are confident that for most patients, remaining home or remaining in a non-acute setting rather than returning to the hospital indicates a better outcome. Although some hospital returns are unavoidable, others may result from poor quality of care, overutilization of care, or inadequate transitional care. Transitional care includes effective discharge planning, transfer of information at the time of discharge, patient assessment and education, and coordination-of-care and monitoring in the post-discharge period. When appropriate care transition processes are in place (for example, a patient is discharged to a suitable location, communication occurs between clinicians, medications are correctly reconciled, timely follow-up is arranged), fewer patients return to an acute care setting, either for an ED visit, observation stay, or hospital readmission during the 30 days post-discharge. Numerous studies have found an association between quality of inpatient or transitional care and early (typically 30-day) readmission rates [991] [992] [993] [994] [995] [996] [997] [998] [999] and ED visits [1000] [1001] [1002] [1003] [1004] for a wide range of conditions including AMI.

In response to the commenters' stated assumption that the AMI EDAC measure may have been developed out of concern for the use of observation stays and ED visits in lieu of readmission without evidence that either are being substituted for readmissions, we reiterate that we developed the measure to provide a broad perspective on post-discharge events. The goal of the measure is not to prevent hospitals from keeping patients in the ED or observation units; it is to help patients and providers understand variation among hospitals in the days that are spent by patients in acute care settings

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following a discharge for AMI, as discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24574 through 24576).

Comment: A commenter noted they appreciate our responsiveness to the concerns of the NQF's Scientific Methods Panel and thereby increased the case minimum to 50 patients to improve the intraclass correlation coefficient (ICC) result but suggested that measures should have a minimum ICC reliability threshold of 0.6 or higher. The commenter noted that reaching 0.6 or higher for this measure would require a minimum of 300 cases, which would in turn exclude too many hospitals from the measure and therefore believe it is not appropriate for use in the Hospital IQR Program.

Response: We thank the commenter for their feedback. We agree that is it important to balance the need to include as many hospitals as possible while maintaining acceptable measure reliability. We would like to further clarify that during the NQF Spring 2021 Measure Evaluation Meeting, the NQF Scientific Methods Panel Committee indicated that a split-sample ICC threshold of around 0.4 or higher is considered acceptable measure reliability.[1005] As noted previously in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28536), the proposed refinement of increasing the minimum case count from 25 to 50 will increase the ICC with Spearman Brown Adjustment from 0.384 to 0.402, therefore improving the measure's reliability and meeting an acceptable threshold as determined by the NQF Scientific Methods Panel Committee's guidance at that time. As guidance on acceptable reliability is often changing, we will continue to take this into consideration as we conduct routine measure maintenance.

Comment: A few commenters offered recommendations for ongoing reevaluation of the AMI EDAC measure. A commenter recommended we consider how the COVID–19 pandemic may pose challenges to timely discharge, as hospitals may face constraints due to other health care settings (for example, a skilled nursing facility) being unable to promptly accept patients. Another commenter recommended that we should identify methods to address the issue of fewer hospitals meeting the proposed increased minimum case count and suggested that we could remedy this issue by using all-payer claims data to increase the denominator, improve reliability, include additional risk factors, and increase the relevancy of the measure to a broader base of providers and consumers.

Response: We thank the commenter for their feedback to consider the impact of the COVID–19 pandemic on timely discharge, specifically the concern that the pandemic has presented novel circumstances that might extend the length of a patient's stay in situations in which a hospital is ready to discharge a patient to another healthcare setting but is unable to do so because the other setting, for instance, is unable or unwilling to accept new patients due to issues related to COVID–19. The following COVID–19 adjustments have been made to the AMI EDAC measure for 2022 public reporting as technical updates: (1) Exclusion of COVID–19 patients (ICD–10–CM U07.1) from the cohort; (2) claims for ED visits, observation stays, and readmissions with COVID–19 coding (ICD–10–CM U07.1) are not eligible for the AMI EDAC outcome and are excluded; and (3) addition of a new ''History of COVID–19'' risk variable for risk adjustment. The COVID–19 pandemic continues to have significant and enduring effects on the provision of medical care in the country and around the world. It affects care decisions, including readmissions to the hospital. National or regional shortages or changes in healthcare personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or facility-level case mix may affect quality measurement data.[1006] Adjustments to public reporting methodologies and specifications for 2022 help to ensure the intent of the measures is maintained. Further details of COVID–19 adjustment can be accessed by viewing the 2022 Condition-Specific Excess Days in Acute Care Measures Updates and Specifications Report: AMI, HF, and the Pneumonia and 2022 AMI EDAC Measure Code Specifications Supplemental File, both available on the QualityNet website here: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology*.

We appreciate the suggestion of utilizing all-payer claims data to increase the number of hospitals with at least 50 cases, and we will take this into consideration when planning ongoing measure maintenance analyses. Hospitals with fewer than 50 cases for the AMI EDAC measure will continue to receive confidential feedback reports containing measure results to understand their performance.

Comment: A commenter requested that CMS explain their rationale for proposing the case minimum refinements based on reliability concerns for only the AMI EDAC measure and not including the Excess Days in Acute Care after Hospitalization for Pneumonia (NQF #2882) (Pneumonia EDAC) and Excess Days in Acute Care after Hospitalization for Heart Failure (NQF #2880) (Heart Failure EDAC) measures for consistency. The commenter expressed an assumption that the Pneumonia EDAC and Heart Failure EDAC measures would also be affected by the same reliability concerns as the AMI EDAC measure and would therefore need to adopt the same minimum case count to improve reliability.

Response: We thank the commenter for sharing these concerns. We would like to clarify that the NQF Scientific Methods Panel Committee did not raise concerns with reliability regarding the Pneumonia EDAC or Heart Failure EDAC measures, therefore, refinements for these measures were not proposed alongside those for the AMI EDAC measure. During the Spring 2021 project cycle, NQF's Scientific Methods Panel Committee reviewed and passed both Pneumonia EDAC and Heart Failure EDAC measures on reliability with a rating of moderate, and NQF's All-Cause Admissions and Readmissions Standing Committee voted to uphold the Scientific Methods Panel Committee's rating on reliability. Thus, as both Pneumonia EDAC and Heart Failure EDAC measures were found to have met the NQF's Scientific Acceptability criteria, we did not propose reliability related refinements to these measures at this time.[1007] Further details regarding NQF's ratings on reliability for these measures can be accessed here: *https://www.qualityforum.org/Publications/2022/02/All-Cause_Admissions_and_Readmissions_Final_Report_-_Spring_2021_Cycle.aspx*.

[1005] National Quality Forum. Scientific Methods Panel: Spring 2021 Measure Evaluation Meeting Transcript. March 30, 2021. Available at: *https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Docs/Transcript_03302021.aspx*.

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[1007] National Quality Forum. All-Cause Admissions and Readmissions, Spring 2021 Cycle: CDP Report February 14, 2022. Available at: *https://www.qualityforum.org/Publications/2022/02/All-Cause_Admissions_and_Readmissions_Final_Report_-_Spring_2021_Cycle.aspx*.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

7. Summary of Previously Finalized and New Hospital IQR Program Measures

a. Summary of Previously Finalized and New Hospital IQR Program Measures for the FY 2024 Payment Determination

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2024 payment determination:

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TABLE IX.E-09. MEASURES FOR THE FY 2024 PAYMENT DETERMINATION

Short Name	Measure Name	NQF #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Outcome Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days***	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment***	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB****	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158
Claims and Electronic Data Measures		
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* In this final rule, we are finalizing adoption of a refined Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with the FY 2024 payment determination and for subsequent years. We refer readers to section IX.E.5.i. for more detailed discussion.

** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid HWR measure (NQF #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

*** In this final rule, we are finalizing refinements to two current Hospital IQR Program measures—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA and Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We refer readers to sections IX.E.6.a. and IX.E.6.b, respectively, for more detailed discussion.

**** In this final rule, we are finalizing adoption of a refined the MSPB Hospital measure beginning with the FY 2024 payment determination. We refer readers to section IX.E.5.h. for more detailed discussion.

b. Summary of Previously Finalized and New Hospital IQR Program Measures for the FY 2025 Payment Determination

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2025 payment determination:

TABLE IX.E-10. MEASURES FOR THE FY 2025 PAYMENT DETERMINATION

Short Name	Measure Name	NQF #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days***	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment***	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB****	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158
Claims and Electronic Data Measures		
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Hybrid HWM*****	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE******	Hospital Commitment to Health Equity	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
ePC-02*******	Cesarean Birth	N/A
ePC-07/SMM*******	Severe Obstetric Complications	N/A
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Process Measures		
SDOH-1********	Screening for Social Drivers of Health	N/A
SDOH-2********	Screen Positive Rate for Social Drivers of Health	N/A

* In this final rule, we are finalizing adoption of a refined Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with the FY 2024 payment determination and for subsequent years. We refer readers to section IX.E.5.i. for more detailed discussion.
** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid HWR measure (NQF #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.
*** In this final rule, we are finalizing refinements to two current Hospital IQR Program measures—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA and Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We refer readers to sections IX.E.6.a. and IX.E.6.b, respectively, for more detailed discussion.
**** In this final rule, we are finalizing adoption of a refined MSPB Hospital measure beginning with the FY 2024 payment determination. We refer readers to section IX.E.5.h. for more detailed discussion.
***** In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45365), we finalized adoption of the Hybrid HWM measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.
****** In this final rule, we are finalizing the adoption of the Hospital Commitment to Health Equity measure beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to section IX.E.5.a. for more detailed discussion.
******* In this final rule, we are finalizing two eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination: Cesarean Birth and Severe Obstetric Complications. We are finalizing mandatory reporting of these two measures beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.c. and IX.E.5.d., respectively, for more detailed discussion. We also refer readers to section IX.E.10.e. for changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.
******** In this final rule, we are finalizing adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting in the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.b.(1). and IX.E.5.b.(2), respectively, for more detailed discussion.

c. Summary of Previously Finalized and New Hospital IQR Program Measures for the FY 2026 Payment Determination

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2026 payment determination:

TABLE IX.E-11. MEASURES FOR THE FY 2026 PAYMENT DETERMINATION

Short Name	Measure Name	NQF #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days**	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment**	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB***	Medicare Spending Per Beneficiary (MSPB)—Hospital Measure	2158
Claims and Electronic Data Measures		
Hybrid HWM****	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Hybrid HWR*****	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE******	Hospital Commitment to Health Equity	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
ePC-02*******	Cesarean Birth	N/A

d. Summary of Previously Finalized and New Hospital IQR Program Measures for the FY 2027 Payment Determination

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2027 payment determination:

Short Name	Measure Name	NQF #
ePC-07/SMM*******	Severe Obstetric Complications	N/A
HH-ORAE********	Hospital-Harm—Opioid Related Adverse Events	3501e
GMCS********	Global Malnutrition Composite Score	3592e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM*********	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1**********	Screening for Social Drivers of Health	N/A
SDOH-2*********	Screen Positive Rate for Social Drivers of Health	N/A

* In this final rule, we are finalizing adoption of a refined Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with FY 2024 payment determination and for subsequent years. We refer readers to section IX.E.5.i. for more detailed discussion.

** In this final rule, we are finalizing refinements to two current Hospital IQR Program measures—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA and Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We refer readers to sections IX.E.6.a. and IX.E.6.b, respectively, for more detailed discussion.

*** In this final rule, we are finalizing adoption of a refined MSPB Hospital measure beginning with the FY 2024 payment determination. We refer readers to section IX.E.5.h. for more detailed discussion.

**** In the FY 2022 IPPS/LTCH PPS final rule 86 FR 45365, we finalized adoption of the Hybrid HWM measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.

***** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid HWR measure (NQF #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

****** In this final rule, we are finalizing the adoption of the Hospital Commitment to Health Equity measure beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to section IX.E.5.a. for more detailed discussion.

******* In this final rule, we are finalizing adoption of two eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination: Cesarean Birth and Severe Obstetric Complications. We are finalizing mandatory reporting of these two measures beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.c. and IX.E.5.d., respectively, for more detailed discussion. We also refer readers to section IX.E.10.e. for changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

******** In this final rule, we are finalizing the adoption of two eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years: Hospital-Harm—Opioid-Related Adverse Events and Global Malnutrition Composite Score. We refer readers to sections IX.E.5.e. and IX.E.5.f., respectively for more detailed discussion. We also refer readers to section IX.E.10.e. for changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

********* In this final rule, we are finalizing adoption of the Hospital-Level THA/TKA PRO-PM measure. We are finalizing voluntary reporting of the measure across two periods—July 1, 2023 through June 30, 2024 and July 1, 2024 through June 30, 2025—followed by mandatory reporting for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination and for subsequent years. We refer readers to section IX.E.5.g. for more detailed discussion.

********** In this final rule, we are finalizing adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting in the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.b.(1). and IX.E.5.b.(2)., respectively, for more detailed discussion.

TABLE IX.E-12. MEASURES FOR THE FY 2027 PAYMENT DETERMINATION

Short Name	Measure Name	NQF #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days**	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment**	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB***	Medicare Spending Per Beneficiary (MSPB)—Hospital Measure	2158
Claims and Electronic Data Measures		
Hybrid HWM****	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Hybrid HWR*****	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE******	Hospital Commitment to Health Equity	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
ePC-02*******	Cesarean Birth	N/A
ePC-07/SMM*******	Severe Obstetric Complications	N/A
HH-ORAE********	Hospital-Harm—Opioid Related Adverse Events	3501e
GMCS********	Global Malnutrition Composite Score	3592e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM*********	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1**********	Screening for Social Drivers of Health	N/A

Short Name	Measure Name	NQF #
SDOH-2**********	Screen Positive Rate for Social Drivers of Health	N/A

* In this final rule, we are finalizing adoption of the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with the FY 2024 payment determination and for subsequent years. We refer readers to section IX.E.5.i. for more detailed discussion.

** In this final rule, we are finalizing refinements to two current Hospital IQR Program measures—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA and Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We refer readers to sections IX.E.6.a. and IX.E.6.b, respectively, for more detailed discussion.

*** In this final rule, we are finalizing adoption of a refined MSPB-Hospital measure beginning with the FY 2024 payment determination. We refer readers to section IX.E.5.h. for more detailed discussion.

**** In the FY 2022 IPPS/LTCH PPS final rule 86 FR 45365, we finalized adoption of the Hybrid HWM measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.

***** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid HWR measure (NQF #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

****** In this final rule, we are finalizing adoption of the Hospital Commitment to Health Equity measure beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to section IX.E.5.a. for more detailed discussion.

******* In this final rule, we are finalizing adoption of two eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination: Cesarean Birth and Severe Obstetric Complications. We are finalizing mandatory reporting of these two measures beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.c. and IX.E.5.d., respectively, for more detailed discussion. We also refer readers to section IX.E.10.e. for changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

******** In this final rule, we are finalizing the adoption of two eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years: Hospital-Harm—Opioid-Related Adverse Events and Global Malnutrition Composite Score. We refer readers to sections IX.E.5.e. and IX.E.5.f., respectively for more detailed discussion. We also refer readers to section IX.E.10.e. for changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years

********* In this final rule, we are finalizing adoption of the Hospital-Level THA/TKA PRO-PM measure. We are finalizing voluntary reporting of the measure across two periods—July 1, 2023 through June 30, 2024 and July 1, 2024 through June 30, 2025—followed by mandatory reporting for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination and for subsequent years. We refer readers to section IX.E.5.g. for more detailed discussion.

********** In this final rule, we are finalizing adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting in the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.b.(1) and IX.E.5.b.(2)., respectively, for more detailed discussion.

e. Summary of Previously Finalized and New Hospital IQR Program Measures for the FY 2028 Payment Determination and for Subsequent Years

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2028 payment determination and for subsequent years:

TABLE IX.E-13. MEASURES FOR THE FY 2028 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS

Short Name	Measure Name	NQF #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days**	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment**	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB***	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
Claims and Electronic Data Measures		
Hybrid HWM****	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	N/A
Hybrid HWR*****	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE******	Hospital Commitment to Health Equity	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
ePC-02*******	Cesarean Birth	N/A
ePC-07/SMM*******	Severe Obstetric Complications	N/A
HH-ORAE********	Hospital-Harm—Opioid Related Adverse Events	3501e
GMCS********	Global Malnutrition Composite Score	3592e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM*********	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1**********	Screening for Social Drivers of Health	N/A
SDOH-2**********	Screen Positive Rate for Social Drivers of Health	N/A

* In this final rule, we are finalizing adoption of a refined Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with the CY 2022 reporting period/FY 2024 payment determination. We refer readers to section IX.E.5.i. for more detailed discussion.

** In this final rule, we are finalizing refinements to two current Hospital IQR Program measures—Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA and Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)—beginning with the FY 2024 payment determination. We refer readers to sections IX.E.6.a. and IX.E.6.b, respectively, for more detailed discussion.

*** In this final rule, we are finalizing adoption of a refined MSPB Hospital measure beginning with the /FY 2024 payment determination. We refer readers to section IX.E.5.h. for more detailed discussion.

**** In the FY 2022 IPPS/LTCH PPS final rule 86 FR 45365, we finalized adoption of the Hybrid HWM measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.

***** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid HWR measure (NQF #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

****** In this final rule, we are finalizing the adoption of the Hospital Commitment to Health Equity measure beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to section IX.E.5.a. for more detailed discussion.

******* In this final rule, we are finalizing the adoption of two eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination: Cesarean Birth and Severe Obstetric Complications. We are finalizing mandatory reporting of these two measures beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.c and IX.E.5.d, respectively, for more detailed discussion. We also refer readers to section IX.E.10.e. for changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

******** In this final rule, we are finalizing the adoption of two eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years: Hospital-Harm—Opioid-Related Adverse Events and Global Malnutrition Composite Score. We refer readers to sections IX.E.5.e. and IX.E.5.f., respectively for more detailed discussion. We also refer readers to section IX.E.10.e. for changes to our eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

********* In this final rule, we are finalizing adoption of the Hospital-Level THA/TKA PRO-PM measure. We are finalizing voluntary reporting of the measure across two periods—July 1, 2023 through June 30, 2024 and July 1, 2024 through June 30, 2025—, followed by mandatory reporting for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination and for subsequent years We refer readers to section IX.E.5.g. for more detailed discussion.

********** In this final rule, we are finalizing adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure beginning with a voluntary reporting in the CY 2023 reporting period and mandatory reporting in the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We refer readers to sections IX.E.5.b.(1). and IX.E.5.b.(2)., respectively, for more detailed discussion.

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8. Establishment of a Publicly-Reported Hospital Designation To Capture the Quality and Safety of Maternity Care

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28547 through 28550), we proposed to establish a hospital quality designation that we would publicly report on a CMS website beginning in Fall 2023. We proposed this designation would be awarded to hospitals based on their attestation of submission of the Maternal Morbidity Structural measure, which we believe will reflect their commitment to the quality and safety of maternity care they furnish. This will be the first-ever hospital quality designation by HHS or CMS that specifically focuses on maternal health. We proposed this policy in conjunction with Vice President Harris' ''Maternal Health Day of Action'' announcement [1008] which also signaled CMS' intent to establish this proposed ''birthing-friendly'' hospital designation. Additionally, we requested feedback on potential additional activities that we could undertake to advance maternal health equity.

a. The U.S. Maternal Health Crisis

Despite the highest rate of spending on maternity care, maternal mortality rates in the U.S. are among the highest in the developed world. Every year, approximately 700 women die of complications related to pregnancy and childbirth, and over 25,000 women experience severe complications of pregnancy (severe maternal morbidity). [1009] [1010] Approximately one-third of all pregnancy-related deaths occur at the time of delivery and immediately postpartum, with nearly 20 percent occurring between one and six days postpartum.[1011] Yet, three out of five pregnancy-related deaths are considered preventable.[1012]

Racial, ethnic, disability, and geographic disparities intensify the U.S. maternal health crisis. Adverse maternal health outcomes vary considerably by race and ethnicity, and are highest among Black and American Indian/Alaskan Native women, regardless of their income or education levels.[1013] [1014] Black and American Indian/Alaskan Native women die from pregnancy-related causes at a rate two to three times higher [1015] and experience severe maternal morbidity at a rate nearly two

[1008] The White House. (2021). Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. Accessed January 26, 2022. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/.*

[1009] Petersen EE et al. Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017. MMWR Morbidity and Mortality Weekly Report 2019;68:423–29.

[1010] Maternal and Child Health Bureau. Federally Available Data (FAD) Resource Document. Health Resources and Services Administration. Available at: *https://mchb.tvisdata.hrsa.gov/Admin/FileUpload/DownloadContent?fileName=FadResourceDocument.pdf&isForDownload=False.*

[1011] Davis N.L., Smoots A.N., and Goodman D.A. (2019). Pregnancy-Related Deaths: Data from 14 U.S. Maternal Mortality Review Committees, 2008–2017. Available at: *https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/MMR-Data-Brief_2019-h.pdf.*

[1012] The Centers for Disease Control and Prevention. Pregnancy-Related Deaths in the United States. September 2021. Available at: *https://www.cdc.gov/hearher/pregnancy-related-deaths/index.html.*

[1013] Hoyert DL and Miniño AM. Maternal Mortality in the United States: Changes in Coding, Publication, and Data Release. National Vital Statistics Report. Vol 69, No. 2 (Jan. 2020): 1–18.

[1014] Centers for Disease Control and Prevention. Racial/Ethnic Disparities in Pregnancy-Related Deaths — United States, 2007–2016. September 6, 2019. Vol. 68, No. 35. Available at: *https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6835a3-H.pdf.*

[1015] Centers for Disease Control and Prevention. Pregnancy Mortality Surveillance System. Available at: *https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm.* Accessed November 10, 2021.

times higher than their White, Asian Pacific Islander, and Hispanic counterparts.[1016] The COVID–19 pandemic in the U.S. has exacerbated such racial and ethnic disparities in maternal outcomes, likely associated with Black and Hispanic women facing higher rates of economic hardship and reporting higher rates of mental health concerns compared to their White counterparts.[1017] [1018] [1019] [1020] Women with disabilities have a higher mortality risk and significantly higher risk in almost all adverse maternal outcomes compared with women without disabilities.[1021] Finally, geographic disparities in maternal outcomes also exist. Pregnant women who live in rural communities are at higher risk for severe maternal morbidity and about 60 percent more likely to die before, during, or after delivery than those living in urban settings.[1022]

b. HHS Focus on Improving Maternal Health in the U.S.

To build on the previously established HHS Maternal Health Action Plan, the Vice President's nationwide call to action to reduce maternal morbidity and mortality, and ongoing efforts with HHS and across the federal government,[1023] the Administration seeks to use a whole-of-government approach for improving maternal health and advancing maternal health equity that reduces maternal mortality and morbidity, reduces persistent disparities, and among other activities, increases hospital participation in HHS-sponsored maternal health quality improvement initiatives. A critical focus is reducing existing disparities in maternal health outcomes across race, ethnicity, and geographic area. This targeted strategy is further embodied by other efforts spearheaded by the Biden-Harris Administration, including the first-ever Presidential Proclamation in recognition of Black Maternal Health Week in April 2021, as well as the first-ever federal ''Maternal Health Day of Action'' on December 7, 2021. [1024] [1025]

As part of the ''Day of Action,'' Vice President Harris issued a nationwide call to action to reduce maternal mortality and morbidity and made several key announcements, including CMS' intention to establish the proposed hospital designation.[1026] Additionally, we released a quality, safety, and oversight memorandum (QSO–22–05-Hospitals) to state survey agencies. In that memorandum, we encourage hospitals to consider implementation of evidence-based best practices for the management of obstetric emergencies, along with interventions to address other key contributors to maternal health disparities, to support the delivery of equitable, high-quality care for all pregnant and postpartum individuals.[1027] Such best practices include participation in local/regional perinatal quality collaboratives, application of early warning sign tools, and the use of patient safety ''bundles.'' We encourage hospitals to review the guidance and resources provided in the memorandum to assess their own capacity to provide optimal management of obstetric emergencies and to combat maternal health disparities.

As part of our commitment to reducing high maternal morbidity and mortality rates, the Hospital IQR Program adopted the Maternal Morbidity Structural measure in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365). This measure is designed to determine hospital participation in a state or national Perinatal Quality Improvement (QI) Collaborative and implementation of patient safety practices or bundles through that QI initiative. As noted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365), hospital participation in QI collaboratives has been shown to be effective in improving the infrastructure surrounding management of obstetric conditions that may lead to severe maternal morbidity or mortality.[1028] Additionally, hospital implementation of related QI efforts has been associated with both enhanced quality and safety of care as well as a reduction in the maternal health disparity gap.

The Maternal Morbidity Structural measure is specified to capture whether hospitals are: (1) Currently participating in a structured state or national Perinatal QI Collaborative; and (2) implementing patient safety practices or bundles as part of these QI initiatives. In reporting on this measure, hospitals respond ''Yes,'' ''No,'' or ''N/A (our hospital does not provide inpatient labor/delivery care)'' to a two-part question assessing these two topic areas.[1033] Data collection began with

[1016] US Government Accountability Office. MATERNAL MORTALITY Trends in Pregnancy-Related Deaths and Federal Efforts to Reduce Them. March 2020. Available at: *https://www.gao.gov/assets/gao-20-248.pdf*.

[1017] Raman S. COVID–19 Amplifies Racial Disparities in Maternal Health. Roll Call. May 14, 2020. Available at: *https://www.rollcall.com/2020/05/14/covid-19-amplifies-racial-disparities-in-maternal-health/*.

[1018] National Partnership for Women & Families. Black Women's Maternal Health: A Multifaceted Approach to Addressing Persistent and Dire Health Disparities. April 2018. Available at: *https://www.nationalpartnership.org/our-work/health/reports/black-womens-maternal-health.html*.

[1019] Bion X–S. Efforts to Reduce Black Maternal Mortality Complicated by COVID–19. California Health Care Foundation. April 2020. Available at: *https://www.chcf.org/blog/efforts-reduce-black-maternal-mortality-complicated-covid-19/*.

[1020] Getachew Y et al. Beyond the Case Count: The Wide-Ranging Disparities of COVID–19 in the United States The Commonwealth Fund. September 2020. Available at: *https://www.commonwealthfund.org/publications/2020/sep/beyond-case-count-disparities-covid-19-united-states*.

[1021] Brown, Hilary K, ''Disparities in Severe Maternal Morbidity and Mortality—A Call for Inclusion of Disability in Obstetric Research and Health Care Professional Education,'' JAMA Netw Open. 2021;4(12):e2138910. doi:10.1001/jamanetworkopen.2021.38910. Online at: *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787181*.

[1022] White House Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/*.

[1023] HHS Initiative to Improve Maternal Health. *https://aspe.hhs.gov/topics/public-health/hhs-initiative-improve-maternal-health*.

[1024] A Proclamation on Black Maternal Health Week, 2021. Available at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/04/13/a-proclamation-on-black-maternal-health-week-2021/*.

[1025] The White House. (2021). Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. Accessed January 26, 2022. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/*.

[1026] *Ibid*.

[1027] Centers for Medicare & Medicaid Services. Evidence-Based Best Practices for Hospitals in Managing Obstetric Emergencies and Other Key Contributors to Maternal Health Disparities. Accessed December 20, 2021. Available at: *https://www.cms.gov/files/document/qso-22-05-hospitals.pdf*.

[1028] Main, E.K., Cape, V., Abreo, A., Vasher, J., Woods, A., Carpenter, A., Gould, J.B. (2017). Reduction of Severe Maternal Morbidity from Hemorrhage Using a State Perinatal Quality Collaborative. American Journal of Obstetrics and Gynecology, 216(3): 298.e1. Available at: *https://www.ncbi.nlm.nih.gov/pubmed/*28153661.

[1029] Callaghan-Koru JA et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. Obstet Gynecol 2019;134:109–19.

[1030] Main EK et al. Reduction of severe maternal morbidity from hemorrhage using a state perinatal quality collaborative. Am J Obstet Gynecol 2017;216(3):298.e1–298.e11.

[1031] King PL et al. Reducing time to treatment for severe maternal hypertension through statewide quality improvement. Am J Obstet Gynecol 2018;218:S4.

[1032] Main EK et al. Reduction in racial disparities in severe maternal morbidity from hemorrhage in a large-scale quality improvement collaborative. Am J Obstet Gynecol 2020;223:123.e1–14.

[1033] To report on this measure, hospitals will respond to a two-part question: ''Does your hospital

Continued

fourth quarter 2021 data, which hospitals must have reported by May 2022. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365) for more details on the measure.

c. Establishment of a Publicly-Reported Hospital Designation To Capture the Quality and Safety of Maternity Care

In alignment with the announcement made during the ''Maternal Health Day of Action''[1034] we proposed to establish a hospital designation to be publicly reported on a CMS website beginning in Fall 2023. We will give this designation to hospitals that report ''Yes'' to both questions in the Maternal Morbidity Structural measure. This designation will initially be based only on data from hospitals reporting an affirmative attestation to the Maternal Morbidity Structural measure. This will allow us to initially award the designation based on the data hospitals are currently reporting on the Maternal Morbidity Structural measure under the Hospital IQR Program. In future notice and comment rulemaking, we intend to propose a more robust set of metrics for awarding the designation that may include other maternal health-related measures that may be finalized for the Hospital IQR Program measure set in the future. We note that in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28506 through 28515), we proposed to adopt two new electronic clinical quality measures (eCQMs) for the Hospital IQR Program—the Cesarean Birth (ePC–02) and Severe Obstetric Complications (ePC–07)—in sections IX.E.5.c. and IX.E.5.d, respectively, which are discussed in sections IX.E.5.c. and IX.E.5.d., respectively, of this final rule.

Section 1886(b)(3)(B)(viii)(VII) of the Social Security Act requires that the Secretary establish procedures for making information regarding Hospital IQR Program measures available to the public (74 FR 43864; 75 FR 50184 through 50815). We believe adding this designation to a consumer-facing CMS website will allow patients and families to choose hospitals that have demonstrated a commitment to improving maternal health through their participation in related perinatal QI collaboratives and their implementation of best practices that support the delivery of high-quality maternity care.

We invited public comment on this proposal.

Comment: Many commenters supported the creation of a public designation related to maternity care.

Response: We thank commenters for their support of our proposal to establish a maternity care hospital designation to be publicly reported on a CMS website beginning in Fall 2023. We believe that adoption of this designation represents a first step in informing the public in a meaningful and consumer-friendly manner about hospitals' commitment to the provision of high-quality maternity care and it will empower the public to make more informed decisions as to where they choose to obtain care during pregnancy and postpartum (87 FR 28549). We also note that since the publication of the FY 2023 IPPS/LTCH PPS proposed rule, the White House has published the ''White House Blueprint for Addressing the Maternal Health Crisis'' which further outlines how the hospital designation will fit in with the HHS' maternal health strategy.[1035]

Comment: While many commenters supported the creation of the designation, many of these commenters also stated that they believe the attestation-based Maternal Morbidity Structural measure is not sufficient in fully addressing maternal health. The commenters encouraged CMS to, in the near future, push beyond the use of an attestation by incorporating more rigorous quality reporting components that incentivize hospitals to deliver high-quality care and provide consumers with more detailed, reliable data on hospital results in improving maternal health. Several commenters emphasized the importance of including clear, consistent, patient-centered, and evidence-based measures on maternal health and encouraged our engagement with hospitals, clinicians, and consumers to design and apply a maternal health designation. A few commenters expressed support for the designation's potential to increase participation in perinatal quality collaboratives and other quality improvement initiatives. A couple of commenters noted the proposal builds off an existing Hospital IQR Program measure and will therefore mitigate administrative burden for hospitals. A commenter supported the designation's potential to address the issue of maternal hemorrhage and facilitate timely initiation of interventions.

Response: We appreciate commenters' feedback and support for the maternity care hospital designation. We acknowledge and agree that this iteration of the proposed designation is a first step towards informing the public in a meaningful and consumer-friendly manner about maternity care quality, and advancing maternal health equity more broadly, using a measure that was already finalized in the Hospital IQR Program. As we stated in the FY 2023 IPPS/LTCH PPS proposed rule, we intend to propose a more robust set of criteria for awarding the designation in future notice-and-comment rulemaking (87 FR 28549). We thank the commenters for their support and agree that the designation could support greater participation in perinatal quality improvement collaboratives and implementation of best practices. We are committed to engaging with interested parties as we continue to improve upon this designation in future notice-and-comment rulemaking.

Comment: Many commenters did not support the proposal as currently proposed, indicating that the attestation of participation in a perinatal quality improvement collaborative (as captured by the Maternal Morbidity Structural measure) is insufficient to demonstrate hospital maternity care quality. The commenters suggested that participation in quality improvement collaboratives and initiatives should be considered the floor for acceptable maternity care rather than the ceiling. A few of these commenters noted that participation in such collaboratives varies and using it as the basis for the designation may not be meaningful. A few commenters noted that the designation will be particularly unhelpful in states where the vast majority of birthing facilities participate in perinatal quality improvement collaboratives because the designation would not offer distinction in quality among hospitals. Another commenter questioned whether the designation as proposed meaningfully informs patients beyond the information that is currently available and publicly reported. A few commenters stated further concern that, as proposed, the designation will mislead consumers who believe it indicates an exceptional level of quality when it reflects a less stringent

or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care, and has it implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?.'' Further details on this measure can be found in the FY 2022 IPPS/LTCH PPS final rule at 86 FR 45361 through 45365.

[1034] The White House. (2021). Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. Accessed January 26, 2022. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/*.

[1035] White House Blueprint for Addressing the Maternal Health Crisis. (2022). Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf*.

criterion. A commenter noted that some state perinatal quality improvement collaboratives have had to suspend initiatives due to the COVID–19 pandemic and introduction of a designation based on measures or initiatives that are unattainable for many hospitals is not appropriate at this time. Relatedly, a commenter noted that they used to participate in perinatal quality improvement collaboratives but found the cost of paid membership to be a barrier.

Response: We appreciate the commenters' feedback and acknowledge their concerns. As we stated in the FY 2023 IPPS/LTCH PPS proposed rule, at this time we will base the designation only on data from hospitals reporting an affirmative attestation to the Maternal Morbidity Structural measure under the Hospital IQR Program (87 FR 28549). This measure is already reported as part of the Hospital IQR Program measure set (as finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361)) and we believe using an existing measure will reduce burden for hospitals during the first year of the designation which is particularly critical in light of the ongoing public health emergency. This is a first step. In future notice-and-comment rulemaking, we intend to propose a more robust set of metrics for awarding the designation that may include other maternal health-related measures that may be finalized for the Hospital IQR Program measure set (87 FR 28549). In the Biden-Harris Administration Blueprint to Address the Maternal Health Crisis (hereto referred to as the Blueprint), we acknowledge that full-scale adoption of perinatal quality improvement collaboratives has not happened for several reasons: Not all states have been funded to support this key infrastructure; hospitals are not required to adopt these best practices and therefore may struggle to procure the resources needed to implement them; and, hospitals are not externally incentivized to do so.[1036] In the Blueprint, we state our intent to explore opportunities to advance equitable, high-quality maternity care provided by hospitals in several ways, including through this hospital designation and through the FY 2023 President's Budget which, would support a perinatal quality collaborative in every state.[1037] We believe this will further support hospitals in areas where perinatal quality collaboratives have not been available due to resource or access issues. We acknowledge commenters' concerns that participation in perinatal quality improvement collaboratives may vary. However, as stated in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28548) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365), hospital participation in quality improvement collaboratives has been shown to be effective in improving the infrastructure surrounding management of obstetric conditions that may lead to severe maternal morbidity or mortality, and hospital implementation of quality improvement efforts has been associated with both enhanced quality and safety of maternity care as well as a reduction in the maternal health disparity gap. We believe supporting hospital participation in such efforts is critical to addressing maternal health. In addition, we believe that while the Maternal Morbidity Structural measure and the hospital designation do not directly mandate participation in perinatal quality collaboratives and other quality improvement initiatives, they create strong incentives to the over 3,000 participating hospitals and CAHs that voluntarily participate in the Hospital IQR Program to begin active participation if they have not yet done so or to continue participation in such activities that are an important part of improving the quality of maternity care offered in hospitals.

Comment: Several commenters recommended that hospitals that participate in any state, national, or regional quality improvement activities or collaboratives be considered for the designation. A few commenters noted this flexibility is particularly important for rural hospitals, safety net hospitals, and hospitals in states or regions where a perinatal quality improvement collaborative is not available. A commenter suggested that state Medicaid programs may use national or state Alliance for Innovation on Maternal Health (AIM) or other quality improvement initiatives and these should be considered for the designation. A couple of commenters encouraged us to consider recognizing hospitals that already participate in maternal health designation programs as recipients of the CMS designation.

Response: We thank the commenters for their recommendations. We recognize that hospitals are involved in a variety of quality improvement activities. As stated in the FY 2022 IPPS/LTCH PPS final rule, for purposes of the Maternal Morbidity Structural measure in the Hospital IQR Program, we define a State or national perinatal quality improvement collaborative as a Statewide or a multi-State network working to improve women's health and maternal health outcomes by addressing the quality and safety of maternity care (86 FR 45362). (Specifications for the measure are available on the CMS Measure Methodology page under the file name 'Maternal Morbidity Structural Measure Specifications,' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/*Measure-Methodology.) We believe this provides hospitals with some flexibility to identify a perinatal quality improvement collaborative, of which the HRSA-funded AIM Program is one example, in their state or region in addition to national options.[1038] However, we acknowledge that some hospitals, and especially those in rural areas, may lack immediate access to a collaborative. We continue to consider additional measures for future years of the designation. In the interim, we direct commenters and providers to the December 2021 quality, safety, and oversight memo that provides information on a variety of maternity care quality improvement resources.[1039]

Comment: A few commenters stated that the Maternal Morbidity Structural measure has yet to receive NQF endorsement and therefore should not be the only metric used to designate maternity care quality.

Response: We stated in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45364) that section 1886(b)(3)(B)(viii)(IX)(bb) of the Act provides an exception for NQF endorsement that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

[1036] The White House. White House Blueprint for Addressing the Maternal Health Crisis. June 2022. Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.*

[1037] The White House. Budget of the U.S. Government Fiscal Year 2023. Accessed June 24, 2022. Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/03/budget_fy2023.pdf.*

[1038] Health Resources & Services Administration. Alliance for Innovation on Maternal Health (AIM) and Alliance for Innovation on Maternal Health Community Care Initiative (AIM CCI). 2022. Available at: *https://mchb.hrsa.gov/programs-impact/programs/alliance-innovation-maternal-health-aim-community-care-aim-cci.*

[1039] Centers for Medicare & Medicaid Services. Evidence-Based Best Practices for Hospitals in Managing Obstetric Emergencies and Other Key Contributors to Maternal Health Disparities. Accessed December 20, 2021. Available at: *https://www.cms.gov/files/document/qso-22-05-hospitals.pdf.*

We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures that addressed maternal morbidity through hospital participation in perinatal quality improvement initiatives and the implementation of associated bundles or patient safety practices. We found no other feasible and practical measures on the topic of maternal health; therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies. In future notice-and-comment rulemaking, we intend to propose a more robust set of measures for the designation. We believe that the maternal health crisis is urgent, maternal health inequities are unacceptable, and this persistent problem requires prompt action. We will consider commenter suggestions received as part of the related request for comment included in the FY 2023 IPPS/LTCH PPS proposed rule.

Comment: Many commenters questioned the intent and purpose of the designation. A few commenters disagreed with the designation's narrow focus on maternal health. A commenter stated that a ''birthing-friendly'' designation without neonatal health components is inadequate and suggested that a designation that includes maternal and neonatal health care would be most appropriate for such a designation.

Response: We thank the commenters for their feedback. As previously stated, the proposed designation is intended as a first step in our efforts to adopt policies that address maternal health. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28549), we expressed our intent to propose a more robust set of criteria for awarding the designation, such as other maternal health-related measures that may be finalized for the Hospital IQR Program in the future; which could include two maternal health eCQMs–Cesarean Birth and Severe Obstetric Complications– that we are finalizing in this final rule (in sections IX.E.5.c. and IX.E.5.d., respectively). We acknowledge that there may be other measures that could be candidates for the designation, and we reiterate our intention to continue exploring opportunities across future notice-and-comment rulemaking to continue refining the designation so that it remains meaningful and useful for patients and hospitals.

Comment: A few commenters noted that patients often have limited choice in their delivery location, due to, for example, insurance coverage or provider admitting privileges, and questioned whether this designation could therefore be impactful when considering where to deliver. A commenter stated that because Medicare beneficiaries tend to produce relatively few claims for services related to maternity care, the desired impact with the designation is unclear.

Response: We thank these commenters for their feedback. We acknowledge that for some patients, including those in emergent situations, there may not be opportunities to choose the hospital in which they deliver. However, for many patients, there is an opportunity for some choice and we believe it is important to provide meaningful and user-friendly information to help inform those choices. We also note that there are other important uses for collecting and publishing the data, including transparency to incentivize continuous improvement. We appreciate the commenter's feedback that Medicare claims would likely be less useful as sources of quality data for a maternity care quality designation, which is why we have focused on the use of an attestation measure to begin, and will explore potential EHR-based and other quality measure data to base future iterations of the designation.

Comment: Many commenters expressed concern about potential consequences of evolving the designation over time. Several commenters noted that changing the criteria for the designation without properly educating and informing consumers is likely to impact the integrity of the initiative and the perception of care delivered in hospitals with birthing facilities that may gain and then lose designation. A few commenters stated that hospitals may lose their designation, but continue to prominently feature their previous recognition and create a false assurance of quality to consumers. A commenter expressed concern that CMS could choose to add criteria or metrics to the designation from outside of the Hospital IQR Program or quality measures that have not been reviewed or endorsed through the NQF process, both of which they believe could negatively impact the integrity and accuracy of the designation.

Response: We thank the commenters for their feedback, and we acknowledge commenters' concerns about potential evolution of the designation. We understand many public-facing quality indicators and summary scores, such as star ratings, rankings, or grades, undergo revisions over time rather than remain static to continuously improve the data quality, reliability, and validity, as well as to ensure information remain meaningful to users and align with the state of the field. We do not believe that such revisions jeopardize the integrity of the designation. In addition, as participating facilities continue to provide quality data for the Maternal Morbidity Structural measure each year, the designation will be accordingly refreshed to reflect the most current data. We believe that future refinements to the designation will be needed in order to continue to provide hospitals and consumers the opportunity to access timely quality and safety data to inform decision-making. We encourage hospitals to routinely and accurately update public-facing materials related to the designation to provide the most up-to-date information and avoid misleading the public. We additionally intend to provide additional outreach, communication, and educational materials as we rollout and improve upon this designation. We also note that interested parties may review any future new measures included for the designation as they would be proposed through notice-and-comment rulemaking. With regard to concerns about future adoption of measures for the designation that may lack NQF endorsement, while we prioritize measures that are endorsed when available, we reiterate that section 1886(b)(3)(B)(viii)(IX)(bb) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. As noted earlier, we believe the maternal health crisis is urgent, maternal health inequities are unacceptable, and this persistent problem requires immediate action.

Comment: Several commenters requested additional support or consideration for certain hospital and facility types. Several commenters expressed concern that the designation would have unintended consequences for small and rural hospitals as well as hospitals, including Indian Health Service (IHS) hospitals, caring for populations that have been historically underserved. Commenters cautioned that such a designation could potentially exacerbate disparities and limit access in areas where hospitals struggle to maintain labor and delivery units due to low volume. Commenters worried that patients with the means to

seek care elsewhere could bypass local undesignated hospitals due to a perception of low-value care, further reducing the availability and provision of maternity care in those communities. A few commenters requested CMS consider exempting IHS providers from the designation.

A few commenters recommended the designation consider hospital capacity and offer special consideration to low-volume hospitals to avoid penalizing those hospitals by withholding a designation that could improve access to quality maternity care. The commenters noted that rural hospitals may lack the resources to participate in perinatal quality improvement collaboratives. The commenters suggested providing incentives and resources to rural hospitals to collaborate with any nearby hospital to achieve collective designation, thereby allowing more pregnant individuals to seek care at a local hospital. Similarly, another commenter requested CMS set aside funding for technical assistance for rural hospitals and other facilities to fill in gaps in training and workforce shortages that limit a hospital from participating in a perinatal quality improvement collaborative.

A commenter requested clarification on whether IPPS-exempt, self-governing children's hospitals would be eligible for the designation.

Response: We appreciate commenters sharing their concerns. As stated in the FY 2023 IPPS/LTCH PPS proposed rule, geographic disparities in maternal outcomes persist and we recognize the challenges faced by small and rural hospitals that offer maternity care in these areas, as well as poor maternal health outcomes disproportionately affecting rural communities of color, including American Indian/Alaska Native people (87 FR 28548). We additionally appreciate commenters' concerns regarding the resources required to participate in a perinatal quality improvement collaborative and subsequently affirmatively attest to the Maternal Morbidity Structural measure in order to earn the designation. We recognize that rural and low-volume hospitals may face challenges achieving the designation. We intend to work with HRSA to explore approaches that could support maternity care quality improvement in those facilities in the future. In the Blueprint, the Biden-Harris Administration states its intent to improve rural obstetric readiness at hospitals and IHS facilities by developing guidelines and standards so that facilities without obstetric units are still ''obstetric ready,'' expanding HRSA's Rural Maternity and Obstetrics Management Strategies (RMOMS) Program to enhance access to maternal and obstetric care in rural communities, and providing free readily-accessible online obstetrical trainings to HRSA-funded health centers and free clinics to support the delivery of competent preconception, prenatal, intrapartum, and postpartum care.[1040]

With regard to the recommendation to offer financial or technical assistance, we note that the Hospital IQR Program statute does not authorize incentive payments based on performance as it is a pay-for-reporting program. However, with our federal partners, we will explore opportunities to offer technical and other resources to providers. With regard to considerations for hospital capacity, we will consider the suggestions for potential modifications to the designation in the future and explore additional variables that can affect quality of maternity care, including but not limited to delivery volume, staffing capabilities, and levels of risk-appropriate care. Any additional changes would be made through future rulemaking. Regarding a commenter requesting clarification on IPPS-exempt children's hospitals, we note that we use data from participating subsection (d) hospitals and CAHs that voluntarily participate in the Hospital IQR Program for the designation, which means IPPS-exempt children's hospitals are excluded. We further wish to clarify that subsection (d) hospitals participating in the Hospital IQR Program receive credit under the Hospital IQR Program for the reporting of their Maternal Morbidity Structural measure results, whether they attest to the affirmative or not because it is a pay-for-reporting program (86 FR 45365). This designation is in addition to, but separate from, the reporting of the Maternal Morbidity Structural measure. We continue to assess opportunities to improve maternity care quality, safety, and equity through this designation and will consider strategies focused on rural and low-volume hospitals in future notice-and-comment rulemaking.

Comment: Several commenters requested that any measures used to inform the designation be risk-adjusted. Some commenters also requested that publicly reported measure data be disaggregated and stratified across drivers of health. A few commenters requested that publicly reported data from the designation should include indicators for consumers when a hospital delivers care primarily to populations that are disadvantaged and/or underserved by the healthcare system.

Response: We thank the commenters for their feedback. The initial implementation of the designation would be based on the Maternal Morbidity Structural measure, which is an attestation-based measure that is not risk-adjusted or stratified. We will consider the feasibility, applicability, and appropriateness of risk-adjustment and stratification of measures as we continue to develop this designation in future years. We refer readers to the Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—Request for Information in section IX.B. of the preamble of this final rule for more information on CMS' potential use of measure stratification in the future.

Comment: A few commenters recommended CMS develop a monitoring program to inform consumers on the efficacy of the designation, both for hospitals that receive the designation and those that do not. The commenters recommended hospitals that did not receive the designation should be monitored to determine whether a lack of designation may contribute to a reduction in maternity care access and/or quality, including the closure of obstetric units.

Response: We thank commenters for this recommendation and as we monitor hospital performance on the Maternal Morbidity Structural measure and the new designation, we will consider mechanisms to assess the implementation and impact of the designation.

Comment: Several commenters emphasized the importance of engaging interested parties at state, local, and national levels prior to implementing the designation and in advance of making any modifications to the qualification requirements for the designation. Some commenters noted that the designation is likely to lack value to hospitals, patients, and communities without engagement with relevant interested parties across the spectrum of maternal health. Several commenters also expressed disappointment and concern that more outreach was not done prior to the creation of the designation and requested a delay in implementation so that hospitals have time to allocate the resources required to qualify for the designation. A commenter noted that labor and resource shortages resulting from the ongoing COVID–19 PHE continue to impact hospitals and a delay in implementation is needed.

[1040] The White House. White House Blueprint for Addressing the Maternal Health Crisis. June 2022. Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf*.

Response: We appreciate feedback from interested parties and the value it adds to proposals set forth for the Hospital IQR Program. We finalized the adoption of the Maternal Morbidity Structural measure for the Hospital IQR Program in the FY 2022 IPPS/LTCH PPS final rule with a reporting period starting October 1, 2021 (86 FR 45361). We additionally indicated our commitment to a serious focus and rapid action for maternal health improvement (86 FR 45365). We seek to use a whole-of-government approach for improving maternal health and advancing maternal health equity to reduce maternal mortality and morbidity, reduce persistent disparities, and increase hospital participation in evidence-based maternal health quality improvement initiatives. As mentioned earlier, we signaled our intent for this designation in December 2021 alongside Vice President Harris' ''Maternal Health Day of Action.'' It is our intention to consider ongoing opportunities for engagement with interested parties as we continue to improve upon the designation across future years. While we recognize that hospitals may participate in a variety of quality improvement activities with a focus on maternal health and that many hospitals face challenges due to the COVID–19 PHE, we believe that the maternal health crisis is urgent, maternal health inequities are unacceptable, and this persistent problem requires prompt action. Thus, we do not believe delaying the fall 2023 implementation timeframe to launch the hospital designation information to the public is sufficiently responsive nor appropriate.

Comment: A few commenters expressed concern about the reputational impact to birth centers and other non-hospital birthing facilities that may provide especially high-quality care but will be excluded from the designation as they do not participate in the Hospital IQR Program.

Response: We thank the commenters, and we recognize that people may receive maternity care in a non-hospital birthing facility for a variety of reasons. Birth centers, for example, are not subsection (d) hospitals, so they cannot participate in the Hospital IQR Program, and would therefore not be eligible for a designation. We encourage consumers to utilize publicly reported quality information to better understand the quality of maternity services and care available in their communities. We also intend to provide additional outreach, communication, and educational materials as we launch the designation.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

d. Solicitation of Comments on Designation Name and Additional Data Sources To Consider for Purposes of Awarding This Publicly-Reported Hospital Designation

While our ultimate goal is to designate hospitals with demonstrated commitment to the provision of high-quality, safe, and equitable maternity care, we wish to do so in a way that is meaningful and useful to patients and their families as well as clinicians and hospitals. Therefore, we solicited comments on a name for this designation for future years.

In addition as noted previously, we proposed to designate hospital commitment to maternity care quality and safety based initially on data collected on the Maternal Morbidity Structural measure. Our intent is to expand the criteria we use to award this designation so that it more comprehensively captures the quality and safety of the maternity care delivered by hospitals. Other future sources of data potentially include data collected on the two eCQMs we proposed to add to the Hospital IQR Program measure set, or data on other Hospital IQR Program maternal health measures, should such measures be adopted in the future. We also considered the feasibility of including other quality measurement data sources. In particular, we welcomed comments about patient experience measures that could be relevant for this designation, including patient experience measures that are currently in use in other care settings, patient experience measures that have been developed but require additional testing in pilot settings, or other measures of patient experience that would be appropriate for inclusion in the designation.

We invited public comment on these and other potential quality measurement data sources that would be appropriate to include in a designation that captures the quality and safety of maternity care furnished by hospitals, including quality measures used in other quality reporting programs or care delivery settings. In the previous section IX.E.8.c., we address related comments in the discussion of the maternity care hospital designation. This section of this document contains additional comments received related to the designation name and additional sources of data to consider.

Comment: Many commenters shared other recommendations related to potential future iterations of the designation. Many commenters urged CMS to use evidence-based outcome measures to inform a designation instead of the attestation-based Maternal Morbidity Structural measure. Several commenters recommended inclusion of existing levels of maternal care (LoMC) [1041] in the designation, including those already promoted and endorsed by national stakeholder groups, accrediting bodies, and commissions, as an alternative to participation in a perinatal quality improvement collaborative. Another commenter suggested CMS consider other payment models, including trauma activation or a maternal and fetal health disproportionate share reimbursement model that combines U.S. Census indices with Healthcare Effectiveness Data and Information Set (HEDIS) and CCO data. A commenter suggested designated hospitals be required to offer remote patient monitoring to high-risk patients. One commenter believes that the designation would be better managed by an accreditation agency rather than CMS.

Response: We appreciate commenters' suggestions. We note that the Hospital IQR Program specifically uses quality measures to improve the quality of care as a pay-for-reporting program. As previously stated, we intend to continue exploring opportunities to refine the designation for the future based on measures that are meaningful and useful for patients and hospitals.

Comment: A few commenters urged CMS to dedicate sufficient resources to clearly and deliberately communicate with and educate consumers so they are easily able to understand what the designation does and does not indicate. A couple of commenters recommended a consumer-focused campaign with details about the designation and where to find information on which hospitals are designated. The commenters also recommended that such a campaign include resources on safe and healthy birth for consumers who may not have access to a designated facility or may not have a provider with clinical privileges in a designated hospital. A commenter suggested we partner with local health departments and Medicaid offices to share information in multiple formats and languages with consumers.

Response: We agree with commenters about the importance of clear communication, and are dedicated to communicate in a way that is culturally and linguistically appropriate and

[1041] American College of Obstetricians and Gynecologists. Levels of Maternal Care. 2021. Available at: *https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care.*

accessible by people with disabilities, with consumers. We intend to work with hospitals and other interested parties to make information about the designation available and accessible to patients, their families, and communities in a way that clearly describes what the designation means and where they can find additional information and resources.

Comment: Commenters had varying recommendations on whether other maternal health measures proposed for the Hospital IQR Program would be appropriate for inclusion in the designation. Several commenters supported the future inclusion of the Cesarean Birth eCQM and Severe Obstetrics Complications eCQM in the designation. Conversely, a few commenters opposed the potential inclusion of these two eCQMs into the designation citing potential burden concerns. A few commenters specifically noted that they would not support the inclusion of the Cesarean Birth eCQM as part of the designation until it receives NQF endorsement.

Response: We thank commenters for their recommendations on the potential future inclusion of the Cesarean Birth eCQM and Severe Obstetrics Complications eCQM as part of the designation. We will consider these measures as we continue to develop this designation. Any additional measures or data sources would undergo notice-and-comment rulemaking before inclusion in the designation. In regard to NQF endorsement, we remind readers that both of these eCQMs are currently undergoing NQF review and refer readers to our response in sections IX.E.5.c. and IX.E.5.d. to similar comments. While we prioritize measures that are endorsed when available, we reiterate that section 1886(b)(3)(B)(viii)(IX)(bb) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We further reiterate, as stated in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45365) that, given the severity of the maternal morbidity crisis and as there are currently no NQF-endorsed measures that address maternal morbidity through hospital participation in Statewide or national Perinatal QI Collaboratives, we believe it is important to implement this measure as soon as possible.

Comment: Many commenters suggested other measures for inclusion in the designation requirements. Several commenters recommended breastfeeding measures. Several commenters recommended that the designation include a requirement to demonstrate the provision of respectful maternity care, which could include training on cultural competency, implicit bias, and antiracism. A few commenters suggested demonstration of hiring practices that are culturally and community representative. A couple of commenters recommended maternity adaptations of the sixth CAHPS development cycle to track disrespect and related forms of provider behavior. The commenters also suggested Patient Reported Outcome Measures (PROMs) and Patient-Reported Outcome-based Performance Measures (PRO–PMs) measuring the various dimensions of respect and experience of care. Several commenters emphasized the importance of a designation that highlights hospitals providing access to a diverse maternity care workforce. Commenters cited certified nurse midwives and certified midwives, doulas, certified lactation consultants, community health workers, mental health professionals, and substance use treatment clinicians as vital members of the team. Some commenters recommended the designation include a requirement for hospitals to report whether or not they provide access to such providers. A commenter recommended CMS adopt a sufficient minimum staffing rate as a designation criterion to ensure quality and safety in maternity care delivery. One commenter recommended hospitals seeking the designation conduct simulations of urgent or emergency obstetric scenarios, attest that they have regional transport agreements in place, and that emergency department staff are trained in neonatal resuscitation. Another commenter recommended a measure of postpartum patients with new medical conditions who are discharged with at least seven days of medication. Another commenter recommended requiring implementation of the AIM Postpartum Discharge Transition Patient Safety Bundle.[1042] Another commenter suggested a structural measure of hospital participation in Maternal Early Warning System (MEWS) programs.[1043] Another commenter recommended measurement of the rate of completion of two-week postpartum visits. Another commenter recommended a measure of access to a certified lactation consultant. Another commenter suggested a measure of skin-to-skin rates. Another commenter recommended a measure of access to postpartum contraception (NQF #2902) as well as a measure of unexpected complications of the healthy newborn (NQF #0716). A couple of commenters recommended CMS include the establishment of a hemorrhage protocol as a requirement of the designation. Another commenter recommended implementation of a triage acuity tool specifically designed for obstetric units as a component of the designation.

Several commenters expressed concern about the rights of patients and their ability to access medically necessary care. A couple of commenters recommended that any hospitals that receive the designation be required to transparently report any non-medical restrictions on care, including bans on postpartum tubal ligations, offering other forms of postpartum contraception, and treatments for ectopic pregnancy or premature rupture of membranes. The commenters also requested a commitment from designated hospitals to publicly report the number of patients who are denied those forms of care each year. Additionally, the commenters recommended that designated hospitals not be allowed to send away patients with emergency medical conditions and should be required to comply with Emergency Medical Treatment and Labor Act (EMTALA). The commenters further encouraged CMS to utilize Beneficiary and Family Care Quality Improvement Organizations (BFCC–QIOs) and Quality Innovation Network (QIN) QIOs to help patients better understand the quality of care to which they are entitled, work with hospitals to improve delivery of care, assist patients with complaint processes, and help patients understand their rights and hospitals their obligations under EMTALA.

Response: We thank the commenters for their feedback and appreciate their robust recommendations. We note that we recently communicated with hospitals regarding their existing obligations to comply with EMTALA and refer readers to *https://www.cms.gov/files/document/qso-22-*

[1042] American College of Obstetrics and Gynecology. Alliance for Innovation on Maternal Health (AIM). 2014. Available at: *https://www.acog.org/practice-management/patient-safety-and-quality/partnerships/alliance-for-innovation-on-maternal-health-aim.*

[1043] TCHMB. Maternal Early Warning System. Available at: *https://www.tchmb.org/maternal-early-warning-system#:~:text=The%20Maternal%20Early%20Warning%20System,avoiding%20major%20morbidity%20and%20mortality.*

22-hospitals.pdf for more details.[1044] We further reaffirm our ongoing commitment to improving maternal health and note that actions related to many suggestions from commenters are discussed in more detail in the Biden-Harris Administration's Blueprint for Addressing the Maternal Health Crisis, including the call to eliminate coverage gaps for postpartum women by encouraging states to extend Medicaid coverage from 60 days to a full 12 months postpartum.[1045] The Blueprint also discusses plans to address the gaps in our perinatal workforce, including increasing the number of physicians, licensed midwives, doulas, and community health workers in communities that are historically underserved and under-resourced by the healthcare system; providing guidance to states to help them expand access to licensed midwives, doulas, and freestanding birth centers in Medicaid; and encouraging insurance companies to improve reimbursement for and coverage of licensed midwives and perinatal supports, such as doulas and nurse home visits.[1046] Additionally, the FY 2023 President's Budget allocates funds to help train providers on implicit biases as well as culturally and linguistically appropriate care and to educate and empower more pregnant women and families to know the early warning signs of pregnancy-related complications and behavioral health needs.[1047] We appreciate these recommendations as we consider future direction and policy related to the designation for future notice-and-comment rulemaking.

Comment: A commenter recommended future measures be submitted through the Measures Under Consideration (MUC) process.

Response: We thank the commenter for the suggestion and note that measures adopted for the Hospital IQR Program are required to go through the pre-rulemaking process (which includes the MUC process and review of the MAP) in compliance with section 1890A of the Act.

Comment: Another commenter cautioned that hospitals should not be penalized through components in the designation that fail to account for patients who choose to receive care from non-physician practitioners and are then transferred to physician care late in pregnancy due to an advanced complication. The commenter stated that many factors remain outside of the control of the hospital or treating physician and designation components should take this into account. A few commenters urged CMS to maintain facility-level measures under the designation and cautioned against the adoption of physician-level measures.

Response: We acknowledge the commenter's concern and understand the commenter to mean that hospitals may provide care to pregnant patients in labor or delivery who have not previously received care at that hospital and the commenter is concerned about the impact such situations may have on a hospital's ability to earn the designation. At this time, the designation is based solely on affirmative attestation to the Maternal Morbidity Structural measure and we do not believe that situations such as those described by the commenter would negatively affect a hospital's ability to attest to that measure. We further recognize that there are factors beyond the control of hospitals when treating pregnant women, but we believe that the maternal health crisis requires urgent action, and that this designation can support hospital action on maternal health quality improvement activities.

Comment: Several commenters suggested names for the new maternity care hospital designation. A few commenters suggested ''Quality Birthing Hospital'' as a possible name. A commenter recommended use of ''Birth Star Hospital'' or ''Better Birthing Hospital'' to reflect the quality of birthing care. Another commenter suggested ''Quality Care for Birthing People'' while another commenter recommended ''Quality Care and Birth Equity'' or ''Excellence in Birthing Outcomes.'' Another commenter suggested ''Birthing-Conscious Hospital'' to reflect the maternal and neonatal process. Another commenter suggested ''Center of Excellence in Maternity Care.''

Several commenters stated that the designation name should reflect the data it is measuring and meaningfully represent the population of interest. A commenter recommended that the name emphasize our commitment to excellence. Another commenter cautioned against a name that could be mistaken for marketing.

Several commenters were concerned that use of ''birthing-friendly'' was too similar to the Baby-Friendly Hospital Initiative, a program developed by the World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF). The commenters encouraged moving away from use of ''birthing-friendly'' to avoid any potential confusion.

Response: We thank commenters for their suggestions and will take them into consideration for a future name for the designation.

e. Additional Activities To Advance Maternal Health Equity—Request for Information

We are committed to advancing equity for all, including those in historically underserved and under-resourced communities (American Indian or Alaska Native, Asian or Pacific Islander, Black, Hispanic, and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality).

We specifically sought to explore how we can address the U.S. maternal health crisis through policies and programs, including, but not limited to, the Conditions of Participation (CoPs) and through measures in our quality reporting programs. The CoPs are the health and safety standards that Medicare-certified providers and suppliers must meet to receive Medicare and Medicaid payment. CMS has broad statutory authority to establish health and safety regulations for various providers and suppliers; that statutory authority is usually found within the statutory definition of each provider and supplier type. In the case of hospitals, for instance, section 1861(e)(1) through (8) of the Act sets out specified requirements that hospitals must meet; in addition, section 1861(e)(9) of the Act requires hospitals to ''meet[ ] such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.''

We invited public comment on the following:

- CMS outlines best practices in the memorandum to state survey agencies entitled ''Evidence-Based Best Practices for Hospitals in Managing Obstetric

[1044] Centers for Medicare & Medicaid Services Center for Clinical Standards and Quality. QSO–22–22-Hospitals. Reinforcement of EMTALA Obligations specific to Patients who are Pregnant or are Experiencing Pregnancy Loss (QSO–21–22-HospitalsUPDATED JULY 2022). July 2022. Available at: *https://www.cms.gov/files/document/qso-22-22-hospitals.pdf.*

[1045] The White House. White House Blueprint for Addressing the Maternal Health Crisis. June 2022. Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.*

[1046] The White House. White House Blueprint for Addressing the Maternal Health Crisis. June 2022. Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.*

[1047] The White House. Budget of the U.S. Government Fiscal Year 2023. Accessed June 24, 2022. Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/03/budget_fy2023.pdf.*

emergencies and Other Key Contributors to Maternal Health Disparities.'' [1048] What other additional effective best practices or quality improvement initiatives are currently being utilized by hospitals? How else can hospitals improve maternal health outcomes, enhance their quality of maternity care, and reduce maternal health disparities?

- For hospitals that offer inpatient maternity services, including labor and delivery care, how could the CoPs be modified to improve maternity care and address disparities in maternal health outcomes? How would hospitals focus their governance, provider and staff training, and care-delivery activities to effectively demonstrate compliance with CoPs related to improving maternal health outcomes? What types of measurable activities targeting maternal health outcomes might demonstrate a reduction in maternal health care disparities or improvement in maternal health care delivery?
- Are there new requirements that could be established in the CoPs that would require hospitals to address and improve the quality of postpartum care and support provided to patients? How can the CoPs specifically address the need to improve behavioral health services and monitoring offered during prenatal and postpartum care?
- Might the potential additional maternal health-focused CoPs have unintended consequences on providers with certain characteristics (such as being located in a rural area or having low-volume)? Please provide details on how certain providers might be differentially affected by potential maternal health CoPs. Are there barriers or facilitators that would influence rural hospital achievement of a publicly-reported maternal health designation that may not relate directly to the quality of services provided? How might maternal health CoPs impact providers considering whether it is feasible or viable to offer labor and delivery services in their area?
- What services and staff training should hospitals without inpatient maternity services have in place in preparation for patients in labor?
- What are the best practices that hospitals are utilizing to educate and conduct outreach to patients in underserved communities to increase access to timely maternity care?
- What are best practices for hospitals to actively engage with patients and their families, community-based organizations, and others within their local community to obtain information on ways to improve maternity care? Are there barriers to such engagement (if so, what are the barriers)?
- Do hospitals provide prevention-related education and community outreach on the specific maternal health conditions that have the greatest impact on disadvantaged and underserved communities?
- How can hospitals review and monitor aggregate data on the maternal health risks of the patient population that they serve? What data should hospitals review related to the maternal health risks of the patient population they serve? What data sharing best practices are required for hospitals to share data with external entities, including local and state health departments, community-based organizations, or other health care providers? How can hospitals connect data collected for mothers and their babies after delivery to support research and evaluation of maternal health care after delivery?
- What challenges are there to collecting data on patients with specific maternal health risks? Can these data be stratified by demographics (for example, race and ethnicity)? In addition, how can these data be used in a hospital's quality improvement efforts, and specifically, in their quality assurance and performance improvement (QAPI) program, to improve maternal health outcomes and advance health equity and reduce disparities within their facility? How can maternity care can be incorporated into an ongoing QAPI program?
- How do hospitals conduct reviews of maternal deaths that have occurred within the facility?
- Are hospitals currently utilizing community health needs assessments to determine the specific maternity care needs and social determinants of health of the patient population that they serve? For those hospitals that are utilizing community health needs assessments, are there certain best practices or examples of ways that this assessment can be used to reduce disparities in maternal outcomes?
- Do hospitals have reporting relationships or mechanisms among primary care physicians, obstetrician-gynecologists, and other health care providers such as nurses and certified nurse midwives, and community-based perinatal workers, such as doulas, for optimal coordination of care?
- Do hospitals have readily available referral relationships and points of contact with community resources or community-based organizations to address additional services that a postpartum patient may need upon discharge? This could include the consideration of behavioral and mental health services or resources to address health-related social needs, such as food insecurity, housing instability, and transportation challenges. If hospitals do not have readily available referral relationships and points of contact within the community, what barriers and facilitators impact hospital relationships with community resources or community-based organizations?
- How do hospitals evaluate their perinatal customer experience? What are best practices that are currently being utilized for getting robust input from patients on their perinatal experience?
- What best practices exist for ensuring systemic racism and biases, including implicit bias, are not perpetuated in maternity care?

We received comments on this topic.

Comment: Commenters provided many recommendations for additional maternal health considerations. These included suggestions on how to effectively disseminate best practices in maternity care, the potential applicability of CoPs related to maternal health outcomes, staff training on antiracism and implicit bias in maternity care, approaches for risk-adjustment and stratification of maternal health data, frameworks for implementing maternal health safety monitoring programs, integration of comprehensive clinical and community-based maternity care delivery systems, opportunities for hospitals to build referral relationships with community-based providers, staffing cross-functional and holistic maternity care teams, and designing customer experience and evaluation tools for maternity care patients and families.

Commenters additionally shared examples from state, local, and regional groups as well as individual hospitals working to improve maternity care. Commenters also urged our pursuit of meaningful, continuous outreach with interested parties to ensure that future maternal health actions are effective and add value to hospitals, patients, and communities.

Response: We appreciate learning about the many meaningful programs and practices hospitals are utilizing across our nation and the commitment to implementation of evidence-based practices to improve maternal health and maternity care delivery. We also

[1048] Evidence-based best practices for hospitals in managing obstetric emergencies and other key contributors to maternal health disparities. U.S. Department of Health and Human Services. *https://www.hhs.gov/guidance/document/evidence-based-best-practices-hospitals-managing-obstetric-emergencies-and-other-key.*

thank commenters for the range of recommendations and measure suggestions. As noted in the Blueprint, every person should have a safe, dignified pregnancy and birth and equitable access to health care before, during, and after pregnancy.[1049] We will consider all input as we continue to develop and make progress in strategies that address maternity care quality, safety, and equity in the Hospital IQR Program, through potential new CoPs, and other CMS activities, and will continue outreach to interested parties on future maternal health actions.

9. Future Considerations

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality and cost improvements through the inpatient hospital setting. We have identified potential future measures for future development, which we believe address areas that are important to stakeholders, but which are not currently covered in the Hospital IQR Program. Therefore, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28550) we sought comment on these potential future considerations, as detailed later in the section.

We also refer readers to the following sections: (1) section IX.A. where we sought comments from stakeholders on the health impacts due to climate change, especially on underserved populations, and how we could potentially support hospitals and health systems to more effectively determine and plan for climate impacts, reduce greenhouse gas emissions, and track progress; (2) section IX.B. where we sought input on overarching principles in measuring healthcare quality disparities in hospital quality programs and value-based purchasing programs; and (3) section IX.C. where we sought input on ongoing ways we can advance digital quality measurement and use of Fast Healthcare Interoperability Resources (FHIR) in quality reporting programs.

a. Potential Future Inclusion of Two Digital National Healthcare Safety Network (NHSN) Measures

The Hospital IQR Program previously included NHSN measures that were finalized for removal from the measure set in the FY 2019 IPPS/LTCH PPS final rule (83 FR 4157 through 41553), and retained in the Hospital-Acquired Condition (HAC) Reduction Program (83 FR 41474 through 41477; 83 FR 41449 through 41452) and the Hospital VBP Program (83 FR 41449 through 41452). We have recently identified two new potential measures that utilize EHR-derived data to help address hospital-based adverse events, specifically, hospital-onset infections.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28550 through 28554), we discussed these two measures in more detail and sought public comment on the future inclusion of these measures in the Hospital IQR Program. We also invited public comment on other aspects of these two measures related to future implementation. In addition, we sought public comment on the application of one or both of these measures in other quality reporting programs, including the HAC Reduction Program, the Hospital VBP Program, the PCHQR Program, and the LTCH QRP.

(1) National Healthcare Safety Network (NHSN) Healthcare-Associated Clostridioides difficile Infection Outcome Measure

(a) Background

Clostridioides difficile [1050] is a bacterium that causes diarrhea, pseudomembranous colitis, and toxic megacolon which can lead to sepsis or death.[1051] [1052] [1053] *Clostridioides difficile* infections (CDI) can be reduced in healthcare settings using a multi-faceted approach, including development of an infrastructure for monitoring CDI, implementation of effective antibiotic stewardship to reduce the use of unnecessary antibiotics, isolation and contact precautions for patients with CDI, performance of environmental cleaning with sporicidal agents, and other measures.[1054] CDI is one of the most common healthcare-associated infections (HAIs) in the U.S.[1055] [1056] At any given time, 1 in 31 patients has an HAI in the U.S., and over a million cases of HAIs are reported every year, making HAIs one of the most common adverse events that occurs in a healthcare setting.[1057] [1058]

As one of the most common HAIs, CDIs are a significant contributor to inpatient morbidity and mortality, particularly among older adults.[1059] Incidence of CDI is higher among White patients, female patients, and patients over 65 years of age.[1060] CDIs result in an estimated 500,000 cases annually and between 15,000 and 20,000 deaths.[1061] Additionally, costs associated with CDIs average about $11,400 per case and can have a significant impact on the U.S. healthcare system.[1062] More broadly, HAIs cost over $9.8 billion dollars annually with CDIs contributing to 15.4 percent, or about $1.5 billion dollars of these total annual costs.[1063] Therefore, we currently require reporting of CDI outcomes, along with other HAIs, in value-based purchasing programs like the Hospital VBP Program and HAC

[1049] The White House. White House Blueprint for Addressing the Maternal Health Crisis. June 2022. Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.*

[1050] The *Clostridioides difficile* bacterium was previously called clostridium difficile. The naming was updated in 2016 due to taxonomic updates.

[1051] Centers for Disease Control and Prevention (CDC). What is C. diff? Available at: *https://www.cdc.gov/cdiff/what-is.html.*

[1052] Centers for Disease Control and Prevention (CDC). *Clostridioides difficile* Infection (CDI) Tracking. Available at: *https://www.cdc.gov/hai/eip/cdiff-tracking.html.*

[1053] Centers for Medicare & Medicaid Services National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=606&sectionNumber=1.*

[1054] Centers for Disease Control and Prevention (CDC) CDI Prevention Strategies. Available at: *https://www.cdc.gov/cdiff/clinicians/cdi-prevention-strategies.html.*

[1055] Kwon, J.H., Olsen, M.A., Dubberke, E.R. (2015). The Morbidity, Mortality, and Costs Associated with Clostridium difficile Infection. Infect Dis Clin North Am. 29(1):123–34. Available at: *https://www.sciencedirect.com/science/article/abs/pii/S0891552014000804?via%3Dihub.*

[1056] Magil, S.S., O'Leary, E., Janelle, S.J., Thompson, D.L., Ghinwa, D., Nadle, J., et al. (2018). Changes in Prevalence of Health Care-Associated Infections in U.S. Hospitals. N Engl J Med. 379:1732–1744. DOI: 10.1056/NEJMoa1801550.

[1057] Magil, S.S., O'Leary, E., Janelle, S.J., Thompson, D.L., Ghinwa, D., Nadle, J., et al. (2018). Changes in Prevalence of Health Care-Associated Infections in U.S. Hospitals. N Engl J Med. 379:1732–1744. DOI: 10.1056/NEJMoa1801550.

[1058] Haque M, Sartelli M, McKimm J, Abu Bakar M. (2018). Health care-associated infections—an overview. Infect Drug Resist. 11:2321–2333. doi:10.2147/IDR.S177247.

[1059] Centers for Disease Control and Prevention. (2018). Analysis and Recommendations on the NHSN *Clostridioides difficile* Outcome. Available at: *https://www.cdc.gov/hicpac/pdf/NHSN-C-diff-H.pdf#:~:text=NHSN%20is%20the%20most%20widely%20used%20secure%2C%20internet-based,decreasing%20in%20contrast%20to%20other%20healthcare-associated%20infections.%202.*

[1060] Lessa FC, Mu Y, Bamberg WM, et al. (2015). Burden of Clostridium difficile infection in the United States. N Engl J Med. 372(9):825–34. doi: 10.1056/NEJMoa1408913.

[1061] Zaver, H.B., Moktan, V.P, Harper, E.P., et al. (2021). Reduction in Health Care Facility—Onset *Clostridioides difficile* Infection: A Quality Improvement Initiative. Mayo Clin Proc Innov Qual Outcomes. 5(6):1066–1074. doi: 10.1016/j.mayocpiqo.2021.09.004.

[1062] Zimlichman E, Henderson D, Tamir O, et al. (2013). Health care-associated infections: a meta-analysis of costs and financial impact on the US health care system. JAMA Intern Med. 173(22):2039–46. doi: 10.1001/jamainternmed.2013.9763.

[1063] Zimlichman E, Henderson D, Tamir O, et al. (2013). Health care-associated infections: a meta-analysis of costs and financial impact on the US health care system. JAMA Intern Med.173(22):2039–46. doi: 10.1001/jamainternmed.2013.9763.

Reduction Program, in order to connect performance on HAI measures with payment adjustments.[1064]

The CDC has developed the National Healthcare Safety Network (NHSN) Healthcare-Associated *Clostridioides difficile* Infection Outcome measure that utilizes EHR-derived data. The goal of this measure is to drive an increase in prevention practices, which would result in fewer CDI cases and reduced morbidity and mortality in patients. We believe this would be especially useful given that most cases of CDIs may be prevented or stopped from spreading to other patients when inpatient facilities utilize infection control steps recommended by the CDC. We believe utilizing the CDC's NHSN reporting and submission infrastructure will impose less administrative burden related to data collection and submission for this measure.

Previously, the Hospital IQR Program included a CDI measure which only required CDI facility-wide Lab-ID event reporting (we refer readers to the FY 2012 IPPS/LTCH PPS final rule, 76 FR 51630 through 51631).[1065] The newly developed version of the measure would improve on the original version of the measure by requiring both microbiologic evidence of CDI in stool and evidence of antimicrobial treatment, whereas the original measure only required CDI facility-wide Lab-ID event reporting. The addition of anti-microbial treatment evidence may provide further validity in the reporting of CDIs, as it serves as a surrogate for test results that were clinically interpreted as true infections.

The NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Healthcare Associated Infections.'' [1066]

Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''Safety'' and ''Wellness and Prevention'' priority areas and aligns with our commitment to a patient-centered approach in quality measurement to ensure that patients are safe and receive the highest quality care.[1067]

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28551 through 28552), we requested feedback on the potential future inclusion of the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure into the Hospital IQR Program measure set to aid in disease monitoring, provide hospitals and patients with more information to inform care delivery, and improve patient outcomes.

(b) Overview of Measure

The NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure would track the development of new CDIs among patients already admitted to healthcare facilities, using algorithmic determinations from data sources widely available in EHRs. Both the original and new measure employ the Standardized Infection Ratio (SIR), a statistic used to track HAIs over time. Along with the SIR, this new measure would also use the Adjusted Ranking Metric (ARM) of hospital-onset CDIs among hospitalized patients. The SIR is a primary summary statistic used by the NHSN to track HAIs, and ARM is a new statistic available for acute care hospitals that accounts for differences in the volume of exposure (specifically, denominator) between facilities. ARM provides complementary information to the SIR as ARM provides the reliability-adjusted number of events and allows for ranking facilities.[1068]

The measure was previously endorsed by MAP on June 11, 2019. The CDC submitted the measure for re-endorsement and it was included in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List),[1069] a list of measures under consideration for use in various Medicare programs. The NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure (MUC2021–098) was reviewed by the NQF MAP Hospital Workgroup on December 15, 2021, and received conditional support pending NQF review and re-endorsement once the revised measure is fully tested.[1070] The MAP Coordinating Committee, which provides direction to the MAP workgroups, concurred with the recommendations of the MAP Hospital Workgroup.[1071] We understand that the CDC intends to submit the measure in the future for NQF review and endorsement.

(c) Data Sources

Hospitals would provide data for this measure from their EHRs. The primary sources of data for determining numerator events include microbiology data (CDI test), medication administration data (CDI antimicrobial treatment), and patient encounter, demographic, and location information.

To facilitate rapid, automated, and secure data exchange, the CDC's NHSN is planning to enable and promote reporting of this measure using FHIR. However, as FHIR capabilities are evolving and not yet uniform across healthcare systems, the CDC is also planning on enabling reporting using the existing Health Level 7 (HL7) Clinical Document Architecture (CDA), and potentially other formats as well to provide all facilities with an option for reporting. We are also working with the CDC and ONC to consider how certified health IT can support reporting of data for this measure.

We invited public comment on potential reporting formats for this measure.

(d) Outcome

The outcome of interest is the number of new CDIs among patients already admitted to healthcare facilities.

[1064] Centers for Disease Control and Prevention. (2018). Analysis and Recommendations on the NHSN *Clostridioides difficile* Outcome. Available at: *https://www.cdc.gov/hicpac/pdf/NHSN-C-diff-H.pdf#:~:text=NHSN%20is%20the%20most%20widely%20used%20secure%2C%20internet-based,decreasing%20in%20contrast%20to%20other%20healthcare-associated%20infections.%202.*

[1065] In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41547 through 41553) we removed the NHSN Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome measure (NQF #1717) from the Hospital IQR Program measure set but retained it in the HAC Reduction Program and Hospital VBP Program where it is reported via the CDC NHSN portal (83 FR 41474 through 41477; 83 FR 41449 through 41452). We removed this measure under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program (83 FR 41547).

[1066] Centers for Medicare & Medicaid Services. (2021). Meaningful Measures Hub. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[1067] Centers for Medicare & Medicaid Services. (2021). Quality Measurement Action Plan. Available at: *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf.* We note that Meaningful Measures 2.0 is still under development.

[1068] More information on how ARM and SIR compare can be found at: *https://www.cdc.gov/nhsn/ps-analysis-resources/arm/index.html.*

[1069] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.*

[1070] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.*

[1071] National Quality Forum. (2022). Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care: Final Report. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

(e) Cohort

The measure cohort consists of all patients in the denominator: the expected number of hospital-acquired CDIs based on predictive models using facility- and patient- care location data as predictors.

(f) Exclusion Criteria

The measure excludes patients in the denominator who are not assigned to an inpatient bed in an applicable location, including outpatient clinics and ED visits. Patients <365 days old will also be excluded. As an aside, inpatient rehabilitation locations and inpatient psychiatric locations that have their own CMS Certification Number (CCN) are also excluded from the denominator.

(g) Risk adjustment

The risk adjustment was developed with a statistical risk model. The SIR is risk adjusted for each facility, and the ARM adjusts for volume of exposure between facilities as well as risk adjustment.

(h) Measure Calculation

The measure assesses the development of new CDI among patients already admitted to healthcare facilities.

(i) Numerator and Denominator

The measure's denominator consists of the expected number of hospital-associated CDIs based on predictive models using facility and patient care location data as predictors. The numerator consists of the total observed number of observed CDIs among all inpatients in the facility based on the combination of laboratory test for CDIs plus a therapeutic administered within a window period around the specimen date.

We received comments on this topic.

Comment: Many commenters supported the potential inclusion of the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure in the Hospital IQR Program, stating that it is an improvement over the previously developed CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Outcome Measure and will prevent hospital-acquired infections. A few commenters suggested that we use a phased adoption timeline to give hospitals time to familiarize themselves with reporting measure data. A commenter supported the measure on the condition that certified health IT systems can support data reporting for this measure.

Response: We thank the commenters for their support and suggestions to improve the measure. We will continue to collaborate with the CDC and take the feedback into account for future notice-and-comment rulemaking.

Comment: Several commenters did not support potential inclusion of the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure into the Hospital IQR Program. A commenter opposed adoption because the measure has not received NQF endorsement yet, while another cited uncertainties in the measure definitions. A commenter stated that the measure does not take into account patient factors that increase the risk of developing CDIs. A commenter believed that the technology to report this measure is currently not ready for use. Another commenter did not support providing evidence of antimicrobial treatment for CDI.

Response: We thank the commenters for their feedback and for sharing their concerns. We will continue to collaborate with the CDC and consider this feedback during future notice-and-comment rulemaking.

Comment: Many commenters requested that we postpone adopting the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure until it has been fully tested for validity and reliability and receives NQF endorsement. Several commenters recommended that the measure exclude immunocompromised patients or include risk adjustment based on patients' vulnerability to infections. A commenter recommended that the measure include an exclusion for infections following the use of antibiotics and expressed concern about the measure's impact on rural and low-volume hospitals. A few commenters requested additional clarification and guidance on the measure definitions.

Response: We appreciate the commenters' recommendations. We note that the CDC is still refining the measure specifications. We will take this feedback into consideration as part of future notice-and-comment rulemaking.

Comment: Several commenters were concerned that the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure might have unintended side effects, such as hospitals discouraging health care practitioners from testing or treating patients for CDIs to reduce the number of patients reported in the numerator. To prevent this, a few suggested that we consider working with the CDC to monitor for such practices, or conduct parallel monitoring of complementary metrics. A few commenters expressed concern over the administrative burden of reporting the measure, especially while Fast Healthcare Interoperability Resources (FHIR) and other electronic reporting capabilities are still evolving. A few others suggested that CMS delay mandatory reporting to provide hospitals with enough time to develop their digital reporting capabilities. A commenter recommended that the measure include incentives to hire infection prevention staff given that existing staff are already overworked.

Response: We thank commenters for their feedback and share their concern for avoiding any negative effects on patient care arising from adoption of this measure. We note that this measure is not being proposed for adoption at this time and we requested input as we consider its future inclusion into quality reporting and value-based programs. We will take these comments into consideration as part of future notice-and-comment rulemaking.

Comment: Several commenters shared their feedback on including the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure in the Hospital VBP and HAC Reduction Programs. A few commenters were supportive of including the measure in the value-based purchasing programs, with a commenter noting that including this potential future measure in the Hospital VBP and HAC Reduction Programs could improve quality of care, especially for the most vulnerable patients. A few commenters expressed concern that the new digital measure is not yet ready for the value-based purchasing programs because it lacks baseline testing data, the measure definitions need refinement, and the risk adjustment methodology does not account for patient factors that increase the risk of developing CDIs. They urged that this measure be fully defined, validated, and NQF endorsed prior to implementation. A commenter expressed their belief that CMS should not adopt this measure for the Hospital VBP Program or HAC Reduction Program until hospitals can consistently report using FHIR or testing confirms comparable results using different reporting methods. A commenter sought clarification on how this potential future measure would be weighted in the Hospital VBP and HAC Reduction Programs and how CMS would establish baseline data from which to determine percentiles and rankings that would impact Hospital VBP and HAC Reduction Program payments. Another commenter recommended that the CDC NHSN MRSA and CLABSI measures be maintained in their current programs because they are more specific and better understood by consumers. A commenter stated that CMS should

match the measure definition with the one utilized in the CDI project as part of the CDC's Emerging Infections Program (EIP) and consider general measure alignment with EIP.

Response: We thank commenters for their feedback on the potential future inclusion of this measure in the Hospital VBP and HAC Reduction Programs, and we will consider it for future notice-and-comment rulemaking. We note that specifics about weighting and scoring of any future measures would be proposed in future notice and comment rulemaking.

Comment: A commenter supported the potential inclusion of the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure in the PCHQR Program pending removal of the previously adopted NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure. The commenter also requested that the measure take into consideration that cancer hospitals using PCR testing for CDIs may be penalized unfairly because of the test's higher sensitivity than other testing options. Another commenter supported the measure once it has been fully refined and receives NQF endorsement, stating that the measure would protect patients at cancer hospitals, who as a population are at a higher risk of contracting HAIs.

Response: We thank the commenters for their support and will take their feedback into consideration.

(2) National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

(a) Background

HAIs are the most frequent adverse event in the delivery of healthcare globally.[1072] Incidence rates for most types of HAIs had been declining for several years in the U.S., but the COVID–19 pandemic reversed these trends.[1073] Central line-associated bloodstream infections (CLABSI) declined 31 percent between 2015 and 2019.[1074] Despite this initial trend, the SIR for CLABSI increased in 2020 compared to 2019 in the later quarters due to the pandemic. The NHSN found a 47 percent increase in CLABSI in Quarter 4 of 2020 compared to Quarter 4 of 2019. Overall, CLABSI increased by 24 percent from 2019 to 2020, with the largest increase (50 percent) being found in the ICU. Other types of infections also rose during this period, including hospital-onset MRSA by 15 percent, and Ventilator-Associated Events (VAE) by 35 percent.[1075]

One likely reason for this reversal was the staffing and institutional challenges of caring for COVID–19 patients, which led to a breakdown in previous standards of care. In qualitative studies, infection prevention teams have reported that the pandemic made it difficult to maintain routine CLABSI prevention practices in the ICU.[1076] Another possible reason is that many hospitals underwent large staffing changes, leading to more workers who were not accustomed to the hospital's standard HAI prevention practices.[1077]

The NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure was developed to help further our goal of addressing patient safety outcomes in the hospital care setting. The frequency of hospital fungemia and bacteremia infection rates in the U.S. present unique opportunities for large-scale quality measurement and improvement activities. Statistics on preventability vary but suggest that a considerable proportion of fungemia and bacteremia could be prevented.[1078] The NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure is intended to facilitate safer patient care by increasing awareness of the dangers of fungemia and bacteremia, promoting adherence to recommended clinical guidelines, and encouraging hospitals to track and improve their practices of appropriate monitoring and care delivery for patients. For these reasons, we requested feedback on the potential future inclusion of this measure into the Hospital IQR Program measure set to aid in disease monitoring, provide hospitals and patients with more information to inform care delivery, and improve patient outcomes.

Under CMS' Meaningful Measures Framework, the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Healthcare Associated Infection.'' [1079] Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''Safety'' priority area and aligns with our commitment to a patient-centered approach in quality measurement to ensure that patients are safe and receive the highest quality care.[1080]

While the HAC Reduction Program and Hospital VBP Program use several HAI measures, we believe that the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure may be necessary to build upon previous efforts to reduce HAIs because it encompasses all types of bacteremia and fungemia that occur among already hospitalized patients. Meanwhile, the NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome measure and NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome measure only capture specific types of HAIs.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28553), we invited public comment on the potential use of this measure in the Hospital IQR Program. We are also considering its use in the PCHQR Program and the possibility of replacing the current CLABSI and MRSA measures in the

[1072] Hongsuwan M, Srisamang P, Kanoksil M, et al. (2014). Increasing incidence of hospital-acquired and healthcare-associated bacteremia in northeast Thailand: a multicenter surveillance study. PLoS One. 2014;9(10):e109324. doi:10.1371/journal.pone.0109324.

[1073] Weiner-Lastinger, L., Pattabiraman, V., Konnor, R., Patel, P., Wong, E., Xu, S., Dudeck, M. (2022). The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology, 43(1), 12–25. doi:10.1017/ice.2021.362.

[1074] Centers for Disease Control and Prevention. Central Line-Associated Bloodstream Infections. Accessed on Available at: *https://arpsp.cdc.gov/profile/infections/clabsi?year-select-report=year2019&year-select-hai-state-list=year2019*.

[1075] Centers for Disease Control and Prevention. 2020 National and State Healthcare-Associated Infections Progress Report. Available at: *https://www.cdc.gov/hai/pdfs/progress-report/2020-Progress-Report-Executive-Summary-H.pdf*.

[1076] Fakih, M., Bufalino, A., Sturm, L., Huang, R., Ottenbacher, A., Saake, K. Cacchione, J. (2021). Coronavirus disease 2019 (COVID–19) pandemic, central-line–associated bloodstream infection (CLABSI), and catheter-associated urinary tract infection (CAUTI): The urgent need to refocus on hardwiring prevention efforts. Infection Control & Hospital Epidemiology, 1–6. doi:10.1017/ice.2021.70.

[1077] Fakih, M., Bufalino, A., Sturm, L., Huang, R., Ottenbacher, A., Saake, K. Cacchione, J. (2021). Coronavirus disease 2019 (COVID–19) pandemic, central-line–associated bloodstream infection (CLABSI), and catheter-associated urinary tract infection (CAUTI): The urgent need to refocus on hardwiring prevention efforts. Infection Control & Hospital Epidemiology, 1–6. doi:10.1017/ice.2021.70.

[1078] Dantes RB, Rock C, Milstone AM, Jacob JT, Chernetsky-Tejedor S, Harris AD, Leekha S. (2019). Preventability of hospital onset bacteremia and fungemia: A pilot study of a potential healthcare-associated infection outcome measure. Infect Control Hosp Epidemiol, 40(3):358–361. doi: 10.1017/ice.2018.339.

[1079] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*. We note that Meaningful Measures 2.0 is still under development.

[1080] Centers for Medicare & Medicaid Services. (2021). CMS Quality Measurement Action Plan. Available at: *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf*.

HAC Reduction Program and Hospital VBP Program with the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure.

(b) Overview of Measure

This measure captures the development of new bacteremia and fungemia among patients already admitted to acute care hospitals, using algorithmic determinations from data sources widely available in EHRs.

The NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure was previously endorsed by MAP on June 11, 2019. The CDC submitted the measure for re-endorsement and it was included in the publicly available ''List of Measures Under Consideration for July 15, 2021'' (MUC List),[1081] a list of measures under consideration for use in various Medicare programs. The NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure (MUC2021–100) was reviewed by the NQF MAP Hospital Workgroup on December 15, 2021 and received conditional support pending NQF review and re-endorsement once the revised measure is fully tested.[1082] The MAP Coordinating committee, which provides direction to the MAP workgroups, concurred with the recommendations of the MAP Hospital Workgroup. We understand that the CDC intends to submit the measure in the future for NQF review and endorsement.

(c) Data Sources

The data submission and reporting standard procedures for the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure have been set forth by the CDC for NHSN participation in general and for submission of measure data. Although the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure is not specified as an eCQM, manual data entry is not available. The primary sources of data for determining numerator events include microbiology data (blood culture) and patient encounter, demographic, and location information often located in Admission-Discharge-Transfer data (Fast Healthcare Interoperability Resources (FHIR): Encounter, Patient, Observation, Location).

To facilitate rapid, automated, and secure data exchange, the CDC's NHSN is planning to enable and promote reporting of this measure using FHIR. However, as FHIR capabilities are evolving and not uniform across healthcare systems, the CDC is also planning on enabling reporting using the existing Health Level 7 (HL7) Clinical Document Architecture (CDA), and potentially other formats as well to provide all facilities with an option for reporting. We are also working with the CDC and ONC to consider how certified health IT can support reporting of data for this measure.

We invited public comment on potential reporting formats for this measure.

(d) Outcome

The measures outcome (numerator) is defined as the observed number of HOB events. This is defined as growth of a recognized bacterial or fungal pathogen from a blood culture specimen collected on the 4th calendar day of admission or later (where the date of admission to an inpatient location is calendar day 1).

(e) Cohort

The measures outcome (numerator) is defined as the observed number of hospital-onset bacteremia and fungemia (HOB) events based on predictive models using facility-level factors (community-onset incidence of bacteremia and fungemia, blood culture utilization rates), patient care location, and potentially other data as predictors.

(f) Exclusion Criteria

The measure has two numerator exclusions for patients with previous matching POA bacteremia or fungemia. The first numerator exclusion is HOB infections in which the pathogen is the same species or genus level as the one identified from a blood specimen by culture that the hospital collected in the POA window (defined as hospital calendar day three or earlier). Additionally, if multiple pathogens are identified from the same blood culture, then a match of any of those pathogens to a POA blood pathogen is sufficient to exclude the event from the HOB measure. The measure also excludes patients with a previous HOB event who experience additional HOB events during the same hospital admission. We understand that the CDC may consider additional exclusion criteria for patients with significant risk factors for bacteremia or fungemia infections that are judged not likely to be preventable in rigorous studies.

The measure has one denominator exclusion for data from patients who are not assigned to an inpatient bed in an applicable location. As an aside, denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with a unique CCN from the acute care facility.

(g) Measure Calculation

The measure is an outcome measure that assesses the observed number of HOB events. The measure calculates the ratio of the observed number of HOB events out of the expected number of HOB events based on predictive models using facility and patient care location data as predictors.

We received comments on this topic.

Comment: Many commenters supported the potential inclusion of the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure to the Hospital IQR Program. Numerous commenters stated that the measure would improve patient safety by preventing hospital-acquired infections. Several commenters supported the digital reporting aspect of the measure, expressing their belief that it would make reporting less subjective, make data more traceable, and reduce the administrative burden on hospital staff. A commenter specifically supported the flexibility of reporting via either FHIR or HL7. A commenter supported the measure for adoption in the Hospital IQR Program prior to adding the measure to other quality programs to determine the measure's validity.

Response: We thank the commenters for their support. We will continue to collaborate with the CDC and keep this feedback in mind as part of future notice-and-comment rulemaking.

Comment: Many commenters did not support the potential inclusion of the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure in the Hospital IQR Program. Numerous commenters opposed adoption because the measure has not received NQF endorsement and has yet to be fully tested, while a few others stated that hospitals would incur a significant burden to prepare for reporting electronically sourced data. Several commenters opposed adoption of this measure because it does not take into account patient factors that can increase their risk of developing CDIs. Some expressed concern over potential unintended side effects of this measure, such as the overuse of antibiotics and placing major teaching hospitals at a disadvantage. A commenter cited the uncertainties in measure definitions.

Response: We thank the commenters for their feedback and acknowledge their concerns. We will continue to collaborate with the CDC and consider this feedback as we determine the

[1081] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. Available at: *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.*

[1082] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.*

potential future inclusion of this measure.

Comment: Many commenters expressed their belief that the measure specifications need to be further refined. Several commenters suggested that the measure exclude immunocompromised patients or include risk adjustment based on patients' vulnerability to infections, to account for factors outside of hospitals' control. Several other commenters posed questions about the measure definitions and requested additional clarification. A commenter recommended that the measure account for the type of vascular access device used in patients with HOBs. Several commenters recommended that we postpone adoption of the measure to the Hospital IQR Program until the measure has been validated and NQF endorsed.

Response: We appreciate the recommendations and requests for information. We note that the CDC is still refining the measure specifications. We will take this feedback into consideration as part of future notice-and-comment rulemaking.

Comment: Many commenters were concerned that collecting, reviewing, and reporting data for the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure would be a major burden to hospital staff. Several stated that preparing for digital reporting would be time- and resource-intensive for hospitals while a few others expressed their belief that the measure would be overly burdensome to infection control staff. To improve the measure implementation process, a few commenters recommended that we implement voluntary reporting until the measure has been fully refined, hospitals have time to prepare for reporting, and the technology for data submission is mature.

A few other commenters were concerned about unintended consequences for patient care, including that hospitals might use antimicrobials inappropriately or reduce blood culture orders. To prevent this, A commenter recommended that we consider another measure focused on specific types of bacteremia and fungemia instead. A few commenters recommended that we monitor additional sources of data for surveillance in addition to the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure, such as complementary NHSN metrics.

Response: We appreciate commenters sharing their concerns. We will consider the recommendations for improving the measure and preventing unintended consequences as we consider the potential future inclusion of this measure.

Comment: Several commenters provided feedback on including the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure in the Hospital VBP and HAC Reduction Programs. A few commenters supported the inclusion of this measure in the value-based purchasing programs, with a commenter noting it was a step in the right direction. A few commenters expressed concern that the new digital measure is not yet ready for adoption because it lacks baseline testing data, the measure definitions need refinement, and the risk adjustment methodology does not account for patient factors that increase the risk of developing CDIs. They urged that we ensure that this measure is fully defined, validated, and NQF endorsed prior to implementation. A commenter stated that CMS should not adopt this measure for the Hospital VBP Program or HAC Reduction Program until hospitals can consistently report using FHIR or testing confirms comparable results using different reporting methods. A commenter recommended that the HOB measure replace the CDC NHSN MRSA and CLABSI measures. Another commenter suggested that the CDC NHSN MRSA and CLABSI measures be maintained in the Hospital VBP and HAC Reduction Programs because they are more specific and better understood by consumers. A commenter recommended peer baselining the measure to account for institutional differences in demographics and size.

Response: We thank commenters for their feedback on the potential future inclusion of this measure in the Hospital VBP and HAC Reduction Programs. We will consider all input and note that any future proposal to implement such a measure would be announced through future notice-and-comment rulemaking.

10. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. To successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the previous description. In accordance with the statute, the FY 2023 payment determination will begin the ninth year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

b. Maintenance of Technical Specifications for Quality Measures

For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period of time. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538), in which we summarized how the Hospital IQR Program maintains the technical measure specifications for quality measures and the subregulatory process for incorporation of nonsubstantive updates to the measure specifications to ensure that measures remain up-to-date. We did not propose any changes to these policies in the proposed rule.

The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites). The CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update) contains the technical specifications for electronic clinical quality measures (eCQMs). The Annual Update contains updated measure specifications for the year prior to the reporting period. For example, for the CY 2022 reporting period/FY 2024 payment determination, hospitals are collecting and will submit eCQM data using the May 2021 Annual Update and any applicable addenda. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*.

Hospitals must register and submit quality data through the Hospital Quality Reporting (HQR) System (previously referred to as the QualityNet Secure Portal) (86 FR 45520). The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E.

We also refer readers to section IX.C. of the preamble of the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28486 through 28491) where we requested information on potential actions that would continue to transform the Hospital IQR Program's quality measurement enterprise toward the use of the FHIR standard for data submission.

c. Procedural Requirements

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57168). The previously finalized requirements, including setting up a QualityNet account and the associated timelines, are described at 42 CFR 412.140(a)(2), 42 CFR 412.140(e)(2)(iii), and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51639 through 51640). In the FY 2022 IPPS/LTCH PPS final rule, we finalized the following changes to the Hospital IQR Program regulation text: (1) Update references to the QualityNet website at 42 CFR 412.140(a)(1) and 42 CFR 412.140(c)(2)(i); and (2) use the term ''QualityNet security official'' instead of ''QualityNet Administrator'' at 42 CFR 412.140(a)(2). We did not propose any changes to these policies in the proposed rule.

d. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. We did not propose any changes to these policies in the proposed rule.

e. Reporting and Submission Requirements for eCQMs

(1) Background

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361; 38386 through 38394; 38474 through 38485; and 38487 through 38493), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41567 through 41575; 83 FR 41602 through 41607), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42506), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58940), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45417 through 45421).

In the FY 2018 IPPS/LTCH PPS final rule, we finalized eCQM reporting and submission requirements such that hospitals were required to report only one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38358 through 38361). Those reporting requirements were extended to the CY 2019 reporting period/FY 2021 payment determination through the CY 2021 reporting period/FY 2023 payment determination (83 FR 41603 through 41604; 84 FR 42501 through 42503). In the FY 2020 IPPS/LTCH PPS final rule, we finalized that for the CY 2022 reporting period/FY 2024 payment determination, hospitals would be required to report one, self-selected calendar quarter of data for: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM, for a total of four eCQMs (84 FR 42503 through 42505).

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a progressive increase in the number of required reported quarters of eCQM data, from one self-selected quarter of data to four quarters of data over a three-year period (85 FR 58932 through 58939). Specifically, for the CY 2021 reporting period/FY 2023 payment determination, hospitals were required to report two self-selected calendar quarters of data for each of the four self-selected eCQMs (85 FR 58939). For the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to report three self-selected calendar quarters of data for each eCQM: (a) Three self-selected eCQMs, and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (85 FR 58939). We clarified in the FY 2021 IPPS/LTCH PPS final rule that until hospitals are required to report all four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination, they may submit consecutive or non-consecutive self-selected quarters of data (85 FR 58939). In the FY 2022 IPPS/LTCH PPS final rule, we did not propose any changes to these policies, and we clarified that the self-selected eCQMs must be the same eCQMs across quarters in a given reporting year (86 FR 45418). We did not propose any changes to these policies in the proposed rule. The following Table IX.E–14. summarizes our finalized policy:

TABLE IX.E-14. eCQM DATA PUBLIC REPORTING REQUIREMENTS

Reporting Period / Payment Determination	eCQM Data Publicly Reported
CY 2021 / FY 2023	Two Quarters of Data
CY 2022 / FY 2024	Three Quarters of Data
CY 2023 / FY 2025 (and for subsequent years)	Four Quarters of Data

For the CY 2023 reporting period/FY 2025 payment determination and subsequent years, hospitals are required to report four calendar quarters of data for each eCQM: (a) Three self-selected eCQMs, and (b) the Safe Use of Opioids-Concurrent Prescribing eCQM (85 FR 58939). We did not propose any changes to the eCQM reporting or submission requirements for the CY 2023 reporting period/FY 2025 payment determination.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28555 through 28556), we proposed to modify eCQM reporting and submission requirements beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

(2) Reporting and Submission Requirements for eCQMs for the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28555 through 28556), we proposed to modify the eCQM reporting and submission requirements, such that beginning with the CY 2024 reporting period/FY 2026 payment determination hospitals would be required to report four calendar quarters of data for each required eCQM: (1) Three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the proposed Cesarean Birth eCQM; and (4) the proposed Severe Obstetric Complications eCQM; for a total of six eCQMs. We refer readers to Table IX.E–15. which represents the progressive increase in eCQM reporting requirements, including our proposed changes.

TABLE IX.E-15. CURRENT AND PROPOSED eCQM REPORTING AND SUBMISSION REQUIREMENTS FOR THE CY 2022 REPORTING PERIOD/FY 2024 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS

Reporting Period / Payment Determination	eCQM Data Publicly Reported	Total Number of eCQMs Reported	eCQMs Required to be Reported
CY 2022 / FY 2024	Three Quarters of Data	Four	• Three self-selected eCQMs; and • Safe Use of Opioids—Concurrent Prescribing eCQM[1083]
CY 2023 / FY 2025	Four Quarters of Data	Four	• Three self-selected eCQMs; and • Safe Use of Opioids—Concurrent Prescribing eCQM
Proposed: CY 2024 / FY 2026 (and for subsequent years)	Four Quarters of Data	Six	• Three self-selected eCQMs; and • Safe Use of Opioids—Concurrent Prescribing eCQM; and • Proposed Cesarean Birth eCQM; and • Proposed Severe Obstetric Complications eCQM

This proposal is made in conjunction with our proposals discussed in sections IX.E.5.c. and IX.E.5.d. of the preamble of this final rule, in which we are adopting the Cesarean Birth eCQM and Severe Obstetric Complications eCQM, respectively. Addressing the maternal health crisis, improving maternal health, and closing any gaps that exist as a result of health disparities are among our top goals for quality improvement. The high maternal mortality and morbidity rates in the U.S. necessitate large-scale quality measurement and improvement activities. As part of the effort to reduce maternal mortality and morbidity, we believe it to be important to receive data from all hospitals that provide perinatal care and not to limit data to just hospitals that may self-select those eCQMs. Requiring these eCQMs will also aid in the surveillance of maternal morbidity, mortality, and associated comorbidities and complications as we collect data from all of the hospitals participating in the Hospital IQR Program. Additionally, no maternal morbidity or obstetric complications outcome-based measures exist in national reporting programs, and we believe these measures have the potential to reduce preventable harm and costs associated with adverse events related to perinatal care.

Accordingly, after consideration of public comments and as we are finalizing to adopt the Cesarean Birth eCQM and the Severe Obstetric Complications eCQM, all hospitals participating in the Hospital IQR Program will also be required to report these two eCQMs, increasing the total number of eCQMs reported from four to six beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years as discussed further below.

At the start of required eCQM reporting, we stated that increasing the reporting requirements over time is consistent with our goal of reporting on all eCQMs in the Hospital IQR Program in a stepwise manner while being responsive to hospitals' concerns about timing, readiness, and burden associated with the increased number of measures required to be reported (81 FR 57151 through 57152). With the addition of new measures to the eCQM measure set and increasing the quarters of eCQM data to be reported, our approach to eCQM reporting requirements has supported the goal to incrementally increase eCQM reporting requirements as hospitals continue to gain experience with eCQMs (84 FR 42502). After several years of a steady eCQM reporting requirement, we believe a proposed change to the reporting requirement is timely. We believe that allowing hospitals to continue self-selection of three eCQMs from the measure set for the CY 2024 reporting period/FY 2026 payment determination while requiring reporting of three additional eCQMs provides sufficient flexibility to report on eCQMs applicable to a hospital's quality improvement priorities while also reporting on measures that address the opioid and maternal health crises and that advance health equity. Additionally, we believe that our proposal for hospitals to submit data from three self-selected eCQMs and three required eCQMs continues our approach to collect data derived from EHRs and make progress toward a transition to fully digital quality measurement (86 FR 45345).

We invited public comment on our proposal to increase the number of

[1083] In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28556), we stated in Table IX.E–15. ''Four self-selected eCQMs'' for the eCQMs required to be reported for the CY 2022 reporting period/FY 2024 payment determination. We correct this error in table IX.E–15 of this final rule to ''Three self-selected eCQMs; and Safe Use of Opioids—Concurrent Prescribing eCQM'' in alignment with the language throughout the preamble and as finalized in previous policy.

mandatory measures to be reported from one to three, as described previously, and thereby increase the total number of required eCQMs from four to six.

We refer readers to section IX.H.10.b. of the preamble of this final rule for a discussion of a similar proposal by the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs).

Comment: Several commenters supported our proposal to modify the reporting and submission requirements for eCQMs such that beginning with the CY 2024 reporting period/FY 2026 payment determination hospitals would be required to submit four calendar quarters of data and three required eCQMs. Commenters cited improved transparency and oversight over eCQM submissions, increased data ensuring comparison of quality on priority topics, and enabling hospitals to leverage electronic data collection and reporting to the greatest extent possible.

Response: We thank commenters for their support.

Comment: A commenter supported the proposal to modify eCQM reporting and submission requirements and requested two years of voluntary reporting for the Severe Obstetric Complications eCQM before mandatory reporting.

Response: We thank the commenter for its support of our proposal. Regarding the recommendation to increase the voluntary reporting period from one year to two years, which would delay the start of mandatory reporting of these two finalized perinatal eCQMs, we reiterate that addressing the maternal health crisis, improving maternal health, and closing any gaps that exist as a result of health disparities are among our top goals for quality improvement. By proposing a one-year voluntary reporting period, we sought to balance the need for hospitals and their vendors to prepare for reporting the new eCQMs with the urgency of measuring at a national scale and addressing the high maternal mortality and morbidity rates in the U.S. by requiring mandatory reporting of both the Severe Obstetric Complications eCQM and the Cesarean Birth eCQM beginning with the CY 2024 reporting period/FY 2026 payment determination.

Comment: Several commenters did not support the proposal to modify eCQM reporting and submission requirements, expressing concerns about the pace of change in eCQM reporting and submission proposals, including the amount of time for hospital workflow changes, measure validation, and EHR vendor readiness for eCQM changes. A few commenters recommended a longer timeframe prior to increased requirements for eCQM reporting, including two years of optional reporting prior to mandatory reporting of an eCQM due to the need to address current eCQM challenges before additional eCQMs are required to be reported. Specifically, commenters noted difficulties extracting data from production ready eCQM products delivered by developers, the cost and time associated with eCQM adoption, the demands on hospital resources to meet COVID–19 PHE needs, other CMS quality reporting requirements, and federal EHR requirements given the competing demands on limited hospital quality and health IT resources.

Response: We appreciate commenters' concerns related to additions to the eCQM measure set when some hospitals are experiencing challenges with eCQM reporting and submission. We establish program requirements considering all hospitals that participate in the Hospital IQR Program at a national level, which involves a wide spectrum of capabilities and resources with respect to eCQM reporting. In establishing our eCQM policies, we must balance the needs of hospitals with variable preferences and capabilities. We believe our finalized policy to modify the eCQM reporting and submission requirements will offer opportunities for hospitals that are prepared to voluntarily report the two perinatal eCQMs—Cesarean Birth and Severe Obstetric Complications—to do so for the CY 2023 reporting period/FY2025 payment determination, while providing more than one year for other hospitals to prepare and implement the two perinatal eCQMs for the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. We believe the long-term benefits associated with reporting a full year of data for six eCQMs will outweigh the burdens and that increasing the number of eCQMs for which hospitals are required to report will produce more comprehensive and reliable quality information for patients and providers.

Hospitals have had several years to gain experience reporting eCQM data. In the FY 2021 IPPS/LTCH PPS final rule, we stated that, after holding eCQM reporting and submission policies constant for a number of years in order to give hospitals and their vendors additional time to improve eCQM reporting capabilities, we intended to transition to more robust reporting (85 FR 58934). We reiterate our intention to continue a transition toward more robust eCQM reporting (82 FR 38356 and 84 FR 42502). We believe that increasing the amount of eCQM data reported is in line with our goals to increase electronic reporting of clinical quality measures. We add that eCQM reporting and submission will be supported by technology certified to the 2015 Edition Cures Update that hospitals have had several years to possess, implement, and use in advance of the December 31, 2022 deadline (86 FR 45418). We recognize the cost and time associated with eCQM adoption and refer readers to section XII.B.4.f. of the preamble of this final rule (information collection requirements) for a detailed discussion of our burden estimates associated with the modification of our eCQM reporting and submission requirements.

We acknowledge the commenters' concern that modifying the eCQM reporting and submission requirement for the CY 2024 reporting period/FY 2026 payment determination will require hospital quality and health IT resources to support Hospital IQR Program and other CMS quality reporting requirements and federal EHR requirements, however, we point to the alignment between Hospital IQR Program's reporting requirements and other quality programs, such as the Medicare Promoting Interoperability Program for hospitals and critical access hospitals (CAHs). We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements, zero denominator declaration, and case threshold exemption policies, and the FY 2018 IPPS/LTCH PPS final rule (81 FR 57255 through 57257) where we stated the finalized successful submission requirements in the Hospital IQR Program align with the CQM electronic reporting requirements of Medicare Promoting Interoperability Program for eligible hospitals and CAHs. We will continue to look across all quality programs to identify areas for further streamlining of quality reporting requirements. As referenced in section IX.C., in the ''Continuing to Advance Digital Quality Measurement and Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs—Request for Information,'' we also believe utilizing standardized data for EHR-based measurement (based on the FHIR standard) and aligning where possible with other interoperability requirements can reduce the data collection burden incurred by providers for the purpose of reporting quality measures. We appreciate the comments on, and interest in, opportunities to reduce reporting burden and we will continue to take all comments into

account as we develop future regulatory proposals or other guidance for our quality measurement policies.

We also recognize the burden that the COVID–19 PHE has had on the healthcare system and will continue to monitor the impact that the COVID–19 PHE has on hospitals, including small, rural hospitals. Additionally, if, due to COVID–19 or any other extraordinary circumstance, we emphasize that hospitals may be eligible for an extraordinary circumstances exception (ECE). Hospitals may request an ECE if they are unable to fulfill program requirements due to extraordinary circumstances beyond their control. We refer readers to section IX.E.15 of this final rule, the eCQM ECE resources on the QualityNet website (available at: *https://qualitynet.cms.gov/inpatient/measures/ecqm/participation#tab2*), and 42 CFR 412.140(c)(2) for more information about the Hospital IQR Program's Extraordinary Circumstances Exceptions policy.

Comment: A few commenters did not support the proposal to revise eCQM reporting and submission requirements due to concerns with vendors' timelines to complete upgrades and programming.

Response: We appreciate the commenters' concern, and we urge hospitals to continue to work with their vendor to secure timely delivery of their products. We acknowledge the effort required for hospitals to adopt and implement updated technology to meet the eCQM reporting and submission requirements. However, we respectfully disagree that our proposal would not permit adequate time for product implementation and use. We believe our finalized policy to modify the eCQM reporting and submission requirements will offer opportunities for hospitals that are prepared to voluntarily report the two perinatal eCQMs to do so for the CY 2023 reporting period while providing more than one year for other hospitals to prepare and implement the two perinatal eCQMs for the CY 2024 reporting period/FY 2026 payment determination.

Comment: A few commenters did not support our proposal to modify eCQM reporting and submission requirements due to the cost and time required for EHR changes and updates for small and rural hospitals with limited IT and staffing resources. A commenter requested clarification for hospitals without obstetric departments or who do not perform deliveries and the proposal to require reporting of the two perinatal eCQMs, inquiring if such hospitals replace the measures or omit the perinatal measures.

Response: We acknowledge that facilitating quality improvement for small or rural hospitals can present unique challenges. When selecting eCQMs for inclusion in the measure set we have, and will continue to, consider the recommendations from the rural stakeholders to ensure eCQMs are meaningful to quality improvement for small, rural hospitals (85 FR 58935). As stated in sections IX.E.5.c. and IX.E.5.d., a critical focus in the national approach for improving maternal health and advancing maternal health equity is reducing existing disparities in maternal health outcomes by race, ethnicity, and geography. If a hospital does not have an obstetrics department or has few or no deliveries during a reporting period, the hospital would submit a zero denominator declaration for the measure that allows a hospital to meet the reporting requirements for a particular eCQM if a hospital does not have patients that meet the denominator criteria. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. A QRDA Category I file with patients meeting the initial patient population of the applicable measures, a zero denominator declaration, and/or a case threshold exemption all count toward a successful submission for eCQMs for the Hospital IQR Program (82 FR 38387).

Comment: A few commenters did not support the proposal to modify eCQM reporting and submission requirements due to the as yet determined benefit relative to the administrative costs and the need for more comprehensive, frequent, and actionable eCQM performance feedback.

Response: We thank the commenters for their input and we appreciate their concern, but reiterate our eCQM policies further advance our goal of incrementally increasing the use of EHR data for quality measurement and improvement and is responsive to the feedback of some interested parties urging a faster transition to full electronic reporting (84 FR 42503). We also use a validation process to address concerns about reliability and validity of eCQM data. As stated in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58935), we have conducted an eCQM validation pilot (OMB Control #0938–1022) and completed eCQM data validation from the CY 2017 reporting period and the CY 2018 reporting period. Based on our internal review of the CY 2017 and CY 2018 eCQM data submitted for validation, over half of the measures validated had agreement rates of 80 percent or better. As discussed in section IX.E.11.b. of this final rule, we have an ongoing goal of continuing to assess the accuracy of eCQM measure data (81 FR 57155). Through the finalized modifications to the existing processes for validation of Hospital IQR Program eCQM data discussed in section IX.E.11.b. of this final rule and our finalized policy to modify eCQM reporting and submission requirements we expect to gain a better understanding of how to increase the accuracy of eCQM data by continuing to analyze the validation process and the results (85 FR 58935). We appreciate commenters' statements in support of comprehensive, frequent, and actionable eCQM performance feedback. The implementation of the updated HQR System has provided a more comprehensive platform for eCQM performance feedback as compared to the legacy system. The new HQR System provides various reports and user interfaces to be used by the hospitals to validate their submissions and overall performance. Overall measure outcomes, including the ability to review individual measure outcomes, are available on the eCQM user interface in near real time. Users of the HQR System for eCQM reporting can generate reports real time instead of waiting on the system refresh. This enhanced functionality in the HQR System allows submitters to export a downloadable report for rejected files providing details, including the associated conformance number of the error to make it easier for the submitter to troubleshoot, correct and resubmit the file to achieve the expected outcome.

Comment: A few commenters did not support the proposal to increase the number of mandatory measures, citing concerns about the two proposed perinatal eCQMs and the support for self-selection as an appropriate approach to achieving quality improvement goals. They recommended continuation of the current reporting and submission requirements to provide time for hospitals and the CMS platform to acclimate to the existing requirement to report four quarters of eCQM data.

Response: We appreciate commenters' position regarding mandatory reporting of the two perinatal eCQMs, but note our longstanding view that electronic reporting of quality measure data derived from the EHR will, over time, reduce the burden on hospitals to collect and submit data for the Hospital IQR Program (78 FR 50956). We believe that mandatory reporting of the two perinatal eCQMs in order to gain comprehensive, national measure data

are important tools in addressing the maternal health crisis, as no maternal morbidity or obstetric complications outcome-based measures exist in national reporting programs.

Regarding comments about the CMS platform, we launched the HQR System for reporting quality data (beginning with the CY 2019 reporting period) to improve the experience for program participants (82 FR 38390 and 85 FR 58958). After several years of requiring only one quarter of eCQM data for reporting, at the end of March 2022, we successfully completed the submission period for two quarters of CY 2021 eCQM data. Three quarters of CY 2022 eCQM data will be due by February 28, 2023, and four quarters of CY 2023 eCQM data will not be due until February 29, 2024. We believe this progressive increase in the quarters of data to be reported allows sufficient time for system readiness. In addition, we plan to continue to make changes to improve the system's usability as needed.

Comment: A commenter requested clarification on the proposals for new eCQMs in the Hospital IQR Program given the stated intent to transition to FHIR-based quality measures.

Response: We appreciate the commenter's request for clarification. We consider eCQMs to be a type of digital quality measure (87 FR 28487). As we stated in section IX.C., in the ''Continuing to Advance Digital Quality Measurement and Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs—Request for Information,'' while eCQMs meet the definition for dQMs in many respects, limitations in data standards, requirements, and technology have limited their interoperability. We appreciate the comments on, and interest in, this topic and we will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

Comment: A commenter noted an error in Table IX.E–15 of the preamble of the FY 2023 IPPS/LTCH PPS proposed rule indicating the number of eCQMs required to be reported for the CY 2022 reporting period/FY 2024 payment determination.

Response: We thank the commenter for the comment. In the FY 2023 IPPS/LTCH PPS proposed rule(87 FR 28556), Table IX.E.15, first row, erroneously stated ''Four self-selected eCQMs'' for the eCQMs required to be reported for the CY 2022 reporting period/FY 2024 payment determination. We correct this error in Table IX.E–15 of this final rule to state ''Three self-selected eCQMs; and Safe Use of Opioids—Concurrent Prescribing eCQM'' in alignment with the language throughout the preamble and as finalized in previous policy. To be clear, this was an inadvertent technical error. As finalized in the FY 2020 IPPS/LTCH PPS final rule, four eCQMs are required to be reported for the CY 2022 reporting period/FY 2024 payment determination of which three are self-selected and the Safe Use of Opioids—Concurrent Prescribing eCQM is required (84 FR 42505). In this final rule, we have revised Table IX. E–15 to correct the error.

Comment: A commenter supported the proposal to modify eCQM reporting and submission requirements if CMS mandates the specific eCQMs to be reported, removing the ability of facilities to self-select eCQMs.

Response: We thank the commenter for their input. For the present state, particularly before the implementation of the FHIR standard for eCQM reporting, we believe it is beneficial for hospitals to have the flexibility to self-select eCQMs for reporting and submission in addition to submitting data from high priority eCQMs that are mandatory for reporting. However, as we continue to transition toward more robust eCQM reporting, we will consider the commenter's feedback in future rulemaking.

Comment: A commenter cautioned that public reporting before four quarters of data are reported for a reporting period may not show correct trends or patterns within the quality of care being provided by the organization.

Response: We appreciate the commenter's concern and refer readers to the FY 2020 IPPS/LTCH PPS final rule where we finalized eCQM reporting and submission requirements for the CY 2023 reporting period/FY 2025 payment determination to require hospitals to report four calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (85 FR 58974 through 58975). In the FY 2020 IPPS/LTCH PPS final rule, we also finalized public reporting requirements of eCQMs for the CY 2021 reporting period/FY 2023 payment determination and subsequent years, specifically publicly reporting two quarters of data for the CY 2021 reporting period/FY 2023 payment determination, three quarters of data for the CY 2022 reporting period/FY 2024 payment determination, and for the CY 2023 reporting period/FY 2025 payment determination and subsequent years, we will publicly report four quarters of eCQM data (85 FR 58956). We believe that, beginning with the CY 2023 reporting period, the four quarters of data reported will provide more robust insight on the trends and patterns in the quality of care.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

(3) Continuation of Certification Requirements for eCQM Reporting

(a) Requiring Use of the 2015 Edition and 2015 Edition Cures Update Certification Criteria

In the CY 2021 Physician Fee Schedule (PFS) final rule (85 FR 84825 through 84828), we expanded flexibility under the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and for subsequent years to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized for reporting eCQMs in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41608), or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961). We adopted this flexible approach to encourage hospitals to be early implementers of the 2015 Edition Cures Update while remaining in compliance with Hospital IQR Program data submission requirements and maintaining alignment with requirements in the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs.

In the FY 2022 IPPS/LTCH PPS final rule, beginning with the CY 2023 reporting period/FY 2025 payment determination and subsequent years, we finalized the requirement for hospitals to use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the Hospital IQR Program data (86 FR 45418). We refer readers to the ONC 21st Century Cures Act final rule for additional information about the updates included in the 2015 Edition Cures Update (85 FR 25665). We did not propose any changes to this policy.

(b) Requiring EHR Technology To Be Certified to All Available eCQMs

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505 through 42506), we finalized the requirement that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45418), we finalized the requirement for hospitals to use the 2015 Edition Cures Update beginning

with the CY 2023 reporting period/FY 2025 payment determination, then all available eCQMs used in the Hospital IQR Program for the CY 2023 reporting period/FY 2025 payment determination and subsequent years would need to be reported using certified technology updated to the 2015 Edition Cures Update. We did not propose any changes to this policy.

(4) File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. Under these requirements, hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format, (2) may use third parties to submit QRDA I files on their behalf, and (3) may either use abstraction or pull the data from non-certified sources to then input these data into Certified EHR Technology (CEHRT) for capture and reporting QRDA I. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387).

More specifically regarding the use of QRDA I files, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170) and the FY 2020 IPPS/LTCH PPS final rule (85 FR 58940), in which we stated that we expect QRDA I files to reflect data for one patient per file per quarter, and identified the five key elements that are utilized to identify the file:

- CMS Certification Number (CCN);
- CMS Program Name;
- EHR Patient ID;
- Reporting period specified in the Reporting Parameters Section per the CMS Implementation Guide for the applicable reporting year, which is published on the eCQI Resource Center website at: *https://ecqi.healthit.gov/QRDA*; and
- EHR Submitter ID (beginning with the CY 2021 reporting period/FY 2023 payment determination).

We did not propose any changes to this policy.

(5) Submission Deadlines for eCQM Data

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57172) for our previously adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR Program and the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we finalized the alignment of the Hospital IQR Program eCQM submission deadline with that of the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs—the end of two months following the close of the calendar year—for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. We note the submission deadline will be moved to the next business day if it falls on a weekend or Federal holiday. We did not propose any changes to this policy.

f. Data Submission and Reporting Requirements for Hybrid Measures

(1) Background

The Hospital IQR Program recently adopted hybrid measures into the program's measure set. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized voluntary reporting of the Hybrid Hospital-Wide Readmission (Hybrid HWR) measure for the CY 2018 reporting period. In the FY 2020 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid HWR measure for the Hospital IQR Program (84 FR 42465 through 42481) such that, beginning with the FY 2026 payment determination, hospitals are required to report on the Hybrid HWR measure (84 FR 42479). In the FY 2022 IPPS/LTCH PPS final rule, we also finalized the adoption of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure in a stepwise fashion, beginning with a voluntary reporting period from July 1, 2022 through June 30, 2023, and followed by mandatory reporting from July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination and for subsequent years (86 FR 45365). We also finalized several requirements related to data submission and reporting requirements for hybrid measures under the Hospital IQR Program (84 FR 42506 through 42508). In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28557 through 28558), we proposed changes specific to the zero denominator declarations and case threshold exemptions policies for hybrid measures, as discussed further in the subsequent section.

(2) Certification and File Format Requirements

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 19498 through 19499), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58941), and the CY 2021 PFS final rule (85 FR 84472) for our previously adopted policies regarding certification and file format requirements for hybrid measures in the Hospital IQR Program.

In the CY 2021 PFS final rule (85 FR 84825 through 84828), we finalized flexibility to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41608) or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961, 85 FR 50271), beginning with the CY 2020 reporting period/FY 2022 payment determination and subsequent years. The Hospital IQR Program offers flexibility to meet hybrid measure submission requirements to facilitate successful reporting during the period of transition as providers are updating certified technology to be consistent with the 2015 Edition Update. This flexibility applies to all Hospital IQR Program measures which use EHR data elements to calculate measure rates, including eCQMs and hybrid measures.

In the FY 2022 IPPS/LTCH PPS final rule, to align with the health IT certification requirements for eCQM reporting, we finalized to require hospitals to use only certified technology that has been updated consistent with the 2015 Edition Cures Update to submit hybrid measure data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years (86 FR 45421). We did not propose any changes to these policies in the proposed rule.

(3) Additional Submission Requirements

In the FY 2020 IPPS/LTCH PPS final rule, we finalized allowing hospitals to meet the hybrid measure reporting and submission requirements by submitting any combination of data via QRDA I files, zero denominator declarations, and case threshold exemptions (84 FR 42507). We also finalized applying similar zero denominator declaration and case threshold exemption policies to hybrid measure reporting as we allow for eCQM reporting (84 FR 42507 through 42508).

We note that the ONC 21st Century Cures Act final rule revises the clinical

quality measurement criterion at 45 CFR 170.315(c)(3) to refer to CMS QRDA IGs and remove the HL7® QRDA standard requirements (85 FR 25645). We encourage all hospitals and their health IT vendors to submit QRDA I files early, and to use one of the pre-submission testing tools for electronic reporting, such as submitting test files to the HQR System, to allow additional time for testing and make sure all required data files are successfully submitted by the deadline.

(4) Modification of the Zero Denominator Declarations Policy and Case Threshold Exemptions Policy for Hybrid Measures

As stated in the previous section (section IX.E.10.f.(3).), in the FY 2020 IPPS/LTCH PPS final rule, we finalized applying the zero denominator declarations policy and case threshold exemptions policy to hybrid measure reporting (84 FR 42507 through 42508). Additionally, in the FY 2020 IPPS/LTCH PPS final rule, we indicated that zero denominator declarations and case threshold exemptions would not be necessary during the voluntary reporting periods for hybrid measures but would be an option for hospitals to utilize when hybrid measure reporting became mandatory (84 FR 42508).

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28558), we proposed to remove zero denominator declarations and case threshold exemptions as an option for the reporting of hybrid measures beginning with the FY 2026 payment determination for reasons discussed in the subsequent section. We note that the FY 2026 payment determination is the first year for which hybrid measures, finalized as part of the Hospital IQR Program measure set, will become mandatory for reporting.

Zero denominator declarations allow a hospital whose EHR is capable of reporting hybrid measure data to submit a zero in the denominator for the reporting of a measure if the hospital does not have patients that meet the denominator criteria of that hybrid measure (84 FR 42507). Similarly, the case threshold exemptions policy allows for a hospital with five or fewer inpatient discharges per quarter or 20 or fewer inpatient discharges per year in a given denominator declaration be exempted from reporting on that individual hybrid measure (84 FR 42507). These policies were originally developed for eCQMs and were extended to hybrid measures to ensure hospitals were not penalized for the absence of patients that meet the denominator criteria in the reporting of those measures.

Upon further analysis, however, we do not believe that these policies are applicable for hybrid measures due to the process of reporting the measure data. Hybrid measures do not require that hospitals report a traditional denominator as is required for the submission of eCQMs. Instead, hybrid measures utilize the Initial Patient Population (IPP), as per their measure specifications, that identifies the patients for which hospitals need to extract the EHR data and annual claims data. Additionally, we calculate hybrid measures by merging both the claims and EHR data received. Therefore, since we will confirm the measure cohort to determine whether a hospital has met the denominator criteria, both the zero denominator declaration and the case threshold exemption for hybrid measures will not be applicable to hospitals.

We invited public comment on this proposal.

Comment: A commenter supported our proposal to remove the zero denominator declarations and case threshold exemptions policies for hybrid measures beginning with the FY 2026 payment determination.

Response: We thank the commenter for the support.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

(5) Submission Deadlines for Hybrid Measures

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42508), where we finalized submission deadlines for hybrid measures. We did not propose any changes to these policies in the proposed rule.

g. Sampling and Case Thresholds for Chart-Abstracted Measures

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49709) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. We did not propose any changes to these policies in the proposed rule.

h. HCAHPS Administration and Submission Requirements

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS submission requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS website at *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. We did not propose any changes to these policies in the proposed rule.

i. Data Submission Requirements for Structural Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures. Hospitals are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the HQR System. The data submission period for structural measures begins in April and has the same submission deadline as the fourth calendar quarter chart-abstracted measure deadline. For example, for the FY 2025 payment determination, hospitals would be required to submit the required information between April 1, 2024 and May 15, 2024, with respect to the time period of January 1, 2023 through December 31, 2023.

We note that, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361), for the Maternal Morbidity Structural Measure and the CY 2021 reporting period/FY 2023 payment determination only, we finalized a shortened reporting period from October 1, 2021 through December 31, 2021, while retaining the standard data submission period. Specifically, for the shortened reporting period hospitals will be required to submit the data between April 1, 2022 and May 16, 2022 (we note that May 15, 2022 falls on a weekend and therefore the close of this data submission period is moved to May 16, 2022). Thereafter, we finalized that the reporting period for the Maternal Morbidity Structural Measure will run from: January 1 through December 31 on an annual basis, and that the data submission period will continue to be consistent with our current policy (beginning in April until the same submission deadline as for the fourth calendar quarter of the chart-abstracted measures with respect to the reporting period for

the previous calendar year) (86 FR 45361).

We did not propose any changes to these policies in the proposed rule.

j. Data Submission and Reporting Requirements for CDC NHSN Measures

For details on the data submission and reporting requirements for measures reported via the CDC's National Healthcare Safety Network (NHSN), we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet website.

We note that in the FY 2022 IPPS/LTCH PPS final rule, we finalized the adoption of the COVID–19 Vaccination Among Health Care Personnel measure, beginning in October 2021 for the October 1, 2021 through December 31, 2021 reporting period affecting the FY 2023 payment determination and continuing for each quarter in subsequent years (86 FR 45374). Specific details on data submission for this measure can be found in the CDC's Overview of the Healthcare Safety Component, available at: *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf*. We did not propose any changes to these policies in the proposed rule.

k. Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO–PMs)

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28559 through 28560), in section IX.E.5.g., we proposed the adoption of the hospital-level THA/TKA PRO–PM into the Hospital IQR Program measure set. In this section of the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28559 through 28560), we proposed the reporting and submission requirements for PRO–PM measures as a new type of measure to the Hospital IQR Program.

(1) Submission of PRO–PM Data

(a) Data Submission

In section IX.E.5.g. of the preamble of this final rule, we discuss adoption of the THA/TKA PRO–PM in the Hospital IQR Program. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28527), we proposed that hospitals would have the choice of selecting from multiple submission approaches.

First hospitals may choose to: (1) Send their data to CMS for measure calculation directly; or (2) utilize an external entity, such as through a vendor or registry, to submit their data on behalf of the hospital to CMS for measure calculation. This data submission approach is consistent with stakeholder input received by the measure developer during measure development and comments as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414) which recommended CMS provide multiple options for data submission mechanisms to ensure flexibility.

Whether a hospital chooses to submit the data itself or via a vendor, we would allow a range of file formats. Both hospitals and vendors would use the HQR System for data submission for the THA/TKA PRO–PM. Use of the HQR System leverages existing CMS infrastructure already utilized for other quality measures (such as, HCAHPS or the Sepsis measure). The HQR System allows for data submission using the following file formats: CSV, XML, and a manual data entry option; allowing hospitals and vendors flexibility in data submission. We would provide hospitals with additional detailed information and instructions for submitting data using the HQR System through CMS' existing websites, such as on QualityNet, and through listservs or both.

(b) Data Submission Reporting Requirements

(1) Voluntary Reporting Requirements for the Proposed THA/TKA PRO–PM

As discussed earlier, we proposed a phased implementation approach for adoption of the THA/TKA PRO–PM, with two voluntary reporting periods for the CY 2025 and 2026 reporting periods prior to mandatory reporting beginning with the FY 2028 payment determination. Voluntary reporting prior to mandatory reporting would allow time for hospitals to incorporate the THA/TKA PRO–PM data collection into their clinical workflows and is responsive to stakeholder comments summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414). For each voluntary and subsequent mandatory reporting periods, we would collect data on the THA/TKA PRO–PM in accordance with, and to the extent permitted by, the HIPAA Privacy and Security Rules (45 CFR parts 160 and 164, Subparts A, C, and E), and other applicable federal law.

For hospitals participating in voluntary reporting, hospitals would submit pre-operative PRO data, as well as matching post-operative PRO data for at least 50 percent of their eligible elective primary THA/TKA procedures. The first voluntary reporting period for CY 2025 would include pre-operative PRO data collection from October 3, 2022 through June 30, 2023 (for eligible elective THA/TKA procedures performed from January 1, 2023 through June 30, 2023) and post-operative PRO data collection from October 28, 2023 to August 28, 2024. Hospitals would submit pre-operative data in 2023 and post-operative data in 2024, and we intend to provide hospitals with their results in confidential feedback reports in 2025. Hospitals would submit pre-operative data for the first voluntary reporting three months following the end of the performance period. For post-operative data, hospitals would be required to submit data one month following the end of the performance period. If that day falls on a weekend, submissions will be due the following Monday. For example, for procedures performed between January 1, 2023 and June 30, 2023, pre-operative data will need to be submitted by October 2, 2023. After the initial submission of pre-operative data in the first voluntary period, hospitals would submit both pre-operative and post-operative data by the same day, but for different time periods. For example, hospitals would need to submit: (1) Post-operative data for the first voluntary reporting (for procedures performed between January 1, 2023 and June 30, 2023); and (2) pre-operative data for the second voluntary reporting (for procedures performed between July 1, 2023 and June 30, 2024) of the THA/TKA PRO–PM by September 30, 2024.

The second voluntary reporting period will include pre-operative PRO data collection from April 2, 2023 through June 30, 2024 (for eligible elective THA/TKA procedures performed from July 1, 2023 through June 30, 2024) and post-operative PRO data collection from April 26, 2024 to August 29, 2025. Hospitals would submit pre-operative data in 2024 and post-operative data in 2025, and we noted our intention to provide hospitals with their results in confidential feedback reports in 2026.

We refer readers to Table IX.E–16. for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during voluntary reporting.

TABLE IX.E-16. VOLUNTARY REPORTING OF PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM

Reporting Period	*Performance Period*	*Pre-Operative Data Collection*	*Pre-Operative Data Submission Deadline*	*Post-Operative Data Collection*	*Post-Operative Data Submission deadline*
Voluntary Reporting 1 (2025)	January 1, 2023 through June 30, 2023	October 3, 2022 through June 30, 2023	October 2, 2023	October 28, 2023 to August 28, 2024	September 30, 2024
Voluntary Reporting 2 (2026)	July 1, 2023 through June 30, 2024	April 2, 2023 through June 30, 2024	September 30, 2024	April 26, 2024 to August 29, 2025	September 30, 2025

(2) Mandatory Reporting

Following the two voluntary reporting periods, we proposed the mandatory reporting of the THA/TKA PRO–PM would begin with reporting PRO data for eligible elective THA/TKA procedures from July 1, 2024 through June 30, 2025 (performance period), impacting the FY 2028 payment determination. This initial mandatory reporting would include pre-operative PRO data collection from three months preceding the applicable performance period and from 10 to 14 months after the performance period. For example, pre-operative data from April 2, 2024 through June 30, 2025 (for eligible elective primary THA/TKA procedures from July 1, 2024 through June 30, 2025) and post-operative PRO data collection from April 27, 2025 to August 29, 2026. Pre-operative data submission would occur in 2025 and post-operative data submission in 2026 and we noted our intention to provide hospitals with their results in 2027 before publicly reporting results on the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*, or its successor website. Hospitals would be required to submit 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data as a minimum amount of data for mandatory reporting in the Hospital IQR Program.

We refer readers to Table IX.E–17. for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the mandatory reporting period.

TABLE IX.E-17. MANDATORY REPORTING OF PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM

Reporting Period	*Performance Period*	*Pre-operative Data Collection*	*Pre-operative Data Submission Deadline*	*Post-Operative Data Collection*	*Post-Operative Data Submission Deadline*
Mandatory Reporting (2027)	July 1, 2024 through June 30, 2025	April 2, 2024 through June 30, 2025	September 30, 2025	April 27, 2025 to August 29, 2026	September 30, 2026

We invited public comment on this proposal.

Comment: Several commenters supported the adoption of the Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (THA/TKA PRO–PM), beginning with two voluntary reporting periods followed by mandatory reporting for the reporting period which runs from July 1, 2025, through June 30, 2026, impacting the FY 2028 payment determination. A commenter specifically supported patient-reported outcome measures as a way to assess quality of care and effectiveness from the patient perspective. A commenter generally supported the addition of PRO–PMs into quality programs for clinical scenarios where reliable PRO instruments are available for patients to complete. A commenter supported CMS beginning PRO–PMs using elective procedures. A few commenters specifically supported the adoption of the THA/TKA PRO–PM to the Hospital IQR Program stating it enables patient voices to be heard throughout all phases of their care and recovery, and the measure is important as it includes the patient voice in assessment of outcomes which should be reflected in quality and safety performance.

Response: We thank commenters for their support.

Comment: Several commenters discussed the data collection approach and burden associated with the adoption of the THA/TKA PRO–PM into the Hospital IQR Program. A few commenters supported having multiple modes for data collection and submission of PRO data, including the use of registries. A commenter supported the use of Medicare enrollment data as the source to identify dual eligibility status and variables for risk adjustment.

Many commenters stated specifically that the financial, resource, and labor costs required to collect, track, and submit data would burden hospitals and make successful implementation of the measure difficult. A commenter encouraged delayed adoption for several years to give health systems time to recover resources and staffing impacted by the COVID–19 pandemic. Another commenter expressed concern about small hospitals' ability to collect and report data and suggested we institute technical support as well as financial bonuses for them to utilize. A commenter urged us to consider technical difficulties of adopting a PRO–PM and noted limitations in data infrastructure and EHR systems, and a lack of integration between PRO data. The commenter expressed that progress in this area will require adoption of newer technologies such as machine learning and artificial intelligence to advance the healthcare system.

Response: We thank commenters for their feedback regarding data collection and burden. We agree that having multiple modes of data collection, including use of registries, would be

beneficial to hospitals and reduce burden. We acknowledge the concerns regarding financial, labor, and resource burdens associated with adopting the THA/TKA PRO–PM into the Hospital IQR Program and are seeking to advance patient-centered measurement with as little burden as possible to both providers and patients. While PRO–PMs require providers to integrate data collection into clinical workflows, this integration provides an opportunity for patient-reported outcomes to inform clinical decision making and benefits patients by engaging them in discussions about potential outcomes.

The PRO instruments used to calculate pre- and post-operative scores for this THA/TKA PRO–PM were carefully considered, with extensive stakeholder input from clinicians, to be low burden and are non-proprietary for free use. We will evaluate data collection burden and response rates associated with the THA/TKA PRO–PM. Any feedback on data collection will be considered in future measure development and reevaluation.

We thank commenters for their feedback, and will provide hospitals and other interested parties with more information on data collection and reporting for the THA/TKA PRO–PM through education and outreach activities prior to implementation. We will continue to evaluate feedback on challenges with data collection during voluntary reporting and consider them prior to mandatory reporting.

Comment: A commenter encouraged us to minimize data collection burden to patients by leveraging technology and considering other surveys they are requested to complete, such as HCAHPS. Another commenter requested additional research to understand the burden of the measure on hospitals and patients, including patient survey fatigue, impact of new PRO–PMs on established survey measures like HCAHPS, and acceptable level of burden for use of the measure.

Response: This measure was developed with extensive input from patients, who indicated strong support for a PRO–PM following elective primary THA and TKA. We anticipate data collection for this measure to present a low burden to patients. Regarding survey fatigue, we designed the measure to illuminate a patient's pain and functional status before and after a THA or TKA, which is different than other surveys such as HCAHPS that capture patient experience. Regarding the comment that the THA/TKA PRO–PM may have a reporting impact on other measures, such as HCAHPS, we anticipate a minimal impact to other measures as the THA/TKA PRO–PM's eligible population is procedure-specific which reduces the likelihood of the same patient receiving the HCAHPS and PRO survey. Additionally, the THA/TKA PRO–PM pre-operative assessment (90 to 0 days before surgery) and post-operative assessment (300 to 425 days following surgery) timeframe is different than HCAHPS, which is two weeks after a hospital visit.

Comment: A commenter requested we not adopt the THA/TKA PRO–PM in the Hospital IQR Program until operational challenges identified by CJR participating hospitals are shared publicly, independently analyzed, and addressed. Commenters expressed concern that reporting of the THA/TKA PRO–PM as part of the CJR Model has been challenging and burdensome, resulting in potentially impacting completion rates. A commenter expressed concern response rates will be insufficient to calculate reliable and valid results for comparison of hospital performance. Another commenter stated hospitals have not been able to meet high reporting thresholds and have challenges with survey response rates for the THA/TKA PRO–PM as part of the CJR Model. The commenter recommended CMS analyze pre- and post-operative response rates in the CJR Model and consider ways to support hospitals in increasing responsiveness. Another commenter requested CMS lower the 50 percent submission requirement proposal until it is clear hospitals can produce this.

Response: We appreciate commenters' request for information about use of the measure in the CJR Model. We have gathered feedback from several years of PRO data collection by CJR participating hospitals and applied lessons learned to the THA/TKA PRO–PM proposal for adoption in the Hospital IQR Program, including requiring hospitals to collect and submit fewer variables, allowing hospitals flexibility in data collection options to better integrate into their workflows, and influenced the decision to set the initial reporting threshold to a moderate rate of 50 percent reporting threshold. We highlight that our proposal included two voluntary reporting periods in which we would gather additional feedback from participating hospitals on their experience collecting and submitting data and apply any lessons learned prior to mandatory reporting.

The proposed reporting threshold is based on average response rates for both pre-operative and post-operative surveys collected by participating hospitals in the CJR Model. The proposed reporting threshold for adoption of the measure to the Hospital IQR Program is lower than that currently used in the CJR Model. Additionally, hospitals are not held to reporting thresholds until mandatory reporting. We believe hospitals will therefore have time to develop their data collection and reporting processes. We will continue to consider the appropriate pre- and post-operative matched survey response rate, as well as reporting thresholds. We will evaluate this approach during voluntary reporting and consider adjustments based on feedback prior to mandatory reporting.

Comment: A few commenters supported the proposed phased implementation timeline. A few commenters requested CMS delay mandatory reporting of the measure to allow hospitals time to enhance interoperability and develop processes for successful data collection and submission. A commenter stated the proposed voluntary and mandatory reporting timeline does not provide hospitals sufficient time to gain experience or use results to improve data collection processes. A commenter requested three years of voluntary reporting.

Response: We thank commenters for their support of the phased approach of adopting the THA/TKA PRO–PM in the Hospital IQR Program. We have considered commenters' recommendations regarding voluntary and mandatory reporting timelines. We believe the proposed voluntary and mandatory reporting implementation approach allows hospitals time and notice to make the necessary enhancements to their clinical workflow to successfully report this measure. We highlight that our proposal included two voluntary reporting periods prior to mandatory reporting which balances the need to allow hospitals time to prepare for mandatory reporting with the importance of measuring patients' functional status for these common surgical procedures and the need to make this information publicly available for patient use and quality improvement (87 FR 28528 through 28529). We also note that the proposed first voluntary reporting period uses just six months of data to allow hospitals an opportunity to receive feedback more quickly on, and improve, their data collection and submission processes (87 FR 28528). We intend to carefully consider feedback received during voluntary reporting to inform improvements that may be made for mandatory reporting.

Comment: A commenter requested reimbursement to incentivize reporting

of the THA/TKA PRO–PM and suggested we create a G code for near term use, and a CPT code for permanent use.

Response: We acknowledge commenters' feedback on reimbursement incentives. The Hospital IQR Program statutory authority in section 1886(b)(3)(B)(viii) of the Act does not provide for the ability to award incentive payments for meeting program requirements as it is a pay-for-reporting quality program.

Comment: Another commenter requested CMS share performance results with hospitals transparently and in real time for use in shared decision making.

Response: We confirm that hospitals will receive performance results confidentially as part of both voluntary and mandatory reporting. We encourage hospitals to use these results as part of shared decision making with their patients.

Comment: A commenter expressed concern with response bias and noted accounting for patient socioeconomic status, race, or dual eligibility in the risk model is not adequate to address lack of response.

Response: We thank the commenter for their input regarding health disparities and response bias. We agree that considering the unique experience of populations with social risk factors is important. The measure as proposed accounts for potential non-response bias through inverse probability weighting and considers patient characteristics, including non-white race, dual eligibility, and the AHRQ SES index score.[1084] The AHRQ SES index score is computed using US census data and considers factors including zip code, median household income, percentage of persons below the Federal poverty line, unemployment, education, property value, and percentage of persons in crowded households.[1085] The measure also includes health literacy in the risk model.[1086] We encourage hospitals to consider a variety of PRO data collection methods to support responses from all eligible patients. We will continue to assess the impact of social risk factors on the measure and response rates over time.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

11. Validation of Hospital IQR Program Data

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28560 through 28562), we proposed to update our eCQM validation process. Specifically, we proposed to update our validation requirements for eCQMs from our current requirement that hospitals submit timely and complete data for 75 percent of requested records to submission of timely and complete data for 100 percent of requested records beginning with CY 2022 eCQM data affecting the FY 2025 payment determination and for subsequent years. We note that this will not affect finalized policies with respect to validation of chart-abstracted measures.

a. Background

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41607 through 41608), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42509), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58942 through 58953), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45423 through 45426) for detailed information on and previous changes to chart-abstracted and eCQM validation requirements for the Hospital IQR Program.

In the FY 2017 IPPS/LTCH PPS final rule, we finalized our policy to require submission of at least 75 percent of sampled eCQM medical records in a timely and complete manner for validation (81 FR 57181). To ensure we have adequate data to assess and validate eCQMs, we finalized a requirement that hospitals submit at least 75 percent of sampled eCQM medical records (81 FR 57173 through 57175). In the FY 2021 IPPS/LTCH PPS final rule, we combined the validation processes for eCQMs and chart-abstracted measures, but did not update the threshold submission percent for eCQM medical records (85 FR 58952 through 58944). In that rule, we adopted a policy to remove the separate process for eCQM validation, beginning with the validation affecting the FY 2024 payment determination (for validation commencing in CY 2022 using data from the CY 2021 reporting period) (85 FR 58942 through 58953). Beginning with validation affecting the FY 2024 payment determination and subsequent years, we finalized a policy to incorporate eCQMs into the existing validation process for chart-abstracted measures such that there would be one pool of hospitals selected through random selection and one pool of hospitals selected using targeting criteria, for both chart-abstracted measures and eCQMs (85 FR 58942 through 58953). Under the aligned validation process, a single hospital could be selected for validation of both eCQMs and chart-abstracted measures and is expected to submit data for both chart-abstracted measures and eCQMs (85 FR 58942 through 58953). We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57179 through 57180) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. We did not propose any changes to finalized policies for validation of chart-abstracted measures.

b. Modifications to the Existing Processes for Validation of Hospital IQR Program eCQM Data

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28561), we proposed to update our eCQM validation requirement to require that hospitals selected for validation submit timely and complete data for 100 percent of requested records for eCQM validation beginning with CY 2022 eCQM data, affecting the FY 2025 payment determination and for subsequent years. Hospitals selected for eCQM validation are required to submit timely and sufficient medical records. As finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57178 through 57179), hospitals must submit timely medical records—within 30 days of the records request—to meet eCQM validation requirements. To meet the eCQM validation requirement for sufficient medical records, we proposed to increase the submission threshold from 75 percent to 100 percent beginning with validation of CY 2022 eCQM data affecting the FY 2025 payment determination and for subsequent years.

Ever since validation of eCQMs commenced with CY 2017 data (81 FR 57173 through 57181), all hospitals selected for eCQM validation have successfully submitted at least 75 percent of eCQM medical records

[1084] Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure (Version 1.0 Methodology Report). March 2021.

[1085] Bonito A, Bann C, Eicheldinger C, Carpenter L. Creation of new race-ethnicity codes and socioeconomic status (SES) indicators for Medicare beneficiaries. Final Report, Sub-Task. 2008;2.

[1086] Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure (Version 1.0 Methodology Report). March 2021.

requested by the Clinical Data Abstraction Center (CDAC). Additionally, 95 percent of hospitals selected for participation in eCQM validation for the FY 2020 and FY 2021 payment determinations, which are the most recently available periods, voluntarily and successfully submitted 100 percent of requested records. We believe that increasing the submission threshold from 75 percent to 100 percent of the requested records will support our ongoing goal of continuing to assess the accuracy of eCQM measure data (81 FR 57155). Also, given the high rate of hospitals voluntarily submitting 100 percent of records, we believe updating the submission threshold to 100 percent will be feasible for hospitals.

We note that under our current policy, the accuracy of eCQM data (the extent to which data abstracted for validation matches the data submitted in the QRDA I file) submitted for validation does not affect a hospital's validation score as described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57180 through 57181) and will not be impacted by this finalized update to the submission threshold. We also note that hospitals that fail to submit timely and complete medical records will not meet the eCQM validation requirement and will be subject to payment reduction as described in our previously finalized policy (81 FR 57180). Chart-abstracted data continue to be weighted at 100 percent for payment determination as finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58942 through 58953) and will not be impacted by our proposed modification to the eCQM validation.

The previously finalized eCQM validation requirements, including data submission requirements, are described at 42 CFR 412.140(d)(2)(ii). We also proposed to update the references to ''at least 75 percent'' in this Hospital IQR Program regulation text. Specifically, we proposed to remove the phrase ''at least 75 percent'' and add in its place the phrase ''100 percent.'' We continue to evaluate data submitted for validation for potential future policy changes.

Our previously finalized and newly proposed validation scoring changes are summarized in Table IX.E–18.

TABLE IX.E-18. SUMMARY OF PREVIOUSLY FINALIZED AND PROPOSED eCQM VALIDATION SCORING

	Quarters of Data Required for Validation	Scoring
Previously Finalized Validation Scoring for the FY 2023 Payment Determination (81 FR 57179 through 57181)		
Chart-Abstracted Measures Validation: 400 Random Hospitals + up to 200 Targeted Hospitals	3Q 2020	At least 75% validation score
	4Q 2020	
eCQM Validation: Up to 200 Random Hospitals	1Q 2020 – 4Q 2020	Successful submission of at least 75% of requested medical records
Previously Finalized Validation Scoring for the FY 2024 Payment Determination (85 FR 58942 through 58953)		
COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals	1Q 2021 – 4Q 2021	Chart-Abstracted Measures: at least 75% validation score (weighted at 100%) And eCQMs: Successful submission of 75% of requested medical records
Proposed Update to eCQM Validation Scoring for the FY 2025 Payment Determination and Subsequent Years		
COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals	1Q 2022 – 4Q 2022	Chart-Abstracted Measures: at least 75% validation score (weighted at 100%) And eCQMs: Successful submission of 100% of requested medical records

We invited public comment on this proposal.

Comment: Several commenters supported our proposal to increase the requested medical records for eCQM validation from 75 percent to 100 percent. A commenter emphasized its belief that the vast majority of hospitals already provide 100 percent of requested medical records for eCQM validation.

Response: We thank the commenters for their support.

Comment: A few commenters did not support our proposal. A commenter requested that the 75 percent threshold be maintained until after the end of the COVID–19 PHE. A commenter did not support this modification requesting the current requirement be maintained until scoring is satisfactory enough to score based on performance. Another commenter recommended focusing on accuracy and quality for eCQM validation.

Response: We thank the commenters for their feedback. We acknowledge that hospitals continue to be affected by COVID–19 and we do not wish to further burden these hospitals, but respectfully disagree that we should delay this requirement. As we noted in the FY 2023 IPPS/LTCH PPS proposed rule, ever since validation of eCQMs commenced with CY 2017 data (81 FR 57173 through 57181), all hospitals selected for eCQM validation have successfully submitted at least 75 percent of eCQM medical records requested by the Clinical Data Abstraction Center (CDAC) (86 FR 28561). Additionally, 95 percent of hospitals selected for participation in eCQM validation for the FY 2020 and FY 2021 payment determinations, which are the most recently available periods, voluntarily and successfully submitted 100 percent of requested records (86 FR 28561). Given the high rate of hospitals voluntarily submitting 100 percent of records, we believe updating the submission threshold to 100 percent will be feasible for hospitals (86 FR 28561). We note that under our current policy, the accuracy of eCQM data (the extent to which data abstracted

for validation matches the data submitted in the QRDA I file) submitted for validation does not affect a hospital's validation score as described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57180 through 57181). We will consider the commenters' feedback for future notice-and-comment rulemaking as we continue to improve our current requirements.

Comment: A few commenters shared concerns about vendor-related issues. A commenter requested that hospitals not be penalized for vendor delays. Another commenter requested that vendor systems be thoroughly vetted before these changes are implemented. A commenter noted concerns about the timeliness and value of validation results that they have received back from the validation vendor.

Response: We thank the commenters for their feedback. We encourage hospitals to work closely with their vendors to ensure they are up-to-date with previous and newly finalized requirements. We note that hospitals have had several years to meet the functional and operational demands of eCQM reporting and validation (81 FR 57173 through 57181). We wish to clarify that the accuracy of eCQM data submitted for validation currently does not affect a hospital's payment determination as described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181).

We did not receive any comments on our proposal to update the regulatory language at 42 CFR 412.140(d)(2)(ii) to reflect this change in our validation policy.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

12. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously adopted details on DACA requirements. We did not propose any changes to this policy.

13. Public Display Requirements

a. Background

Section 1886(b)(3)(B)(viii)(VII) of the Act requires the Secretary to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the internet website of CMS. Section 1886(b)(3)(B)(viii)(VII) of the Act also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Our current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*, or its successor website, after a 30-day preview period (78 FR 50776 through 50778). We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49712 through 49713), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41539), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58953) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*.

In the FY 2023 IPPS/LTCH PPS proposed rule, we also proposed a publicly-reported hospital designation on a public-facing website to capture the quality and safety of maternity care. We refer readers to section IX.E.8. of the preamble of this final rule for more details.

b. Public Reporting of eCQM Data

We direct readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58954 through 58959) where we finalized public reporting requirements of eCQM data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. We note that this policy incrementally increases the eCQM data publicly reported to four quarters of data for the CY 2023 reporting period/FY 2025 payment determination and subsequent years. We did not propose any changes to these policies in the proposed rule.

c. Overall Hospital Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Ratings). The Overall Star Ratings utilizes data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital IQR Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule with comment period for details (85 FR 86193 through 86236). We did not propose any changes to these policies in the proposed rule. However, we refer readers to the CY 2023 OPPS/ASC proposed rule [1087] where we proposed to amend the language of 42 CFR 412.190(c) to state that we would use publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior twelve months (instead of the ''prior year'').

14. Reconsideration and Appeal Procedures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We did not propose any changes to these policies in the proposed rule.

15. Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 57182), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38409 through 38411), and 42 CFR 412.140(c)(2) for details on the current Hospital IQR Program ECE policy. We also refer readers to the QualityNet website at: *https://qualitynet.cms.gov* for our current requirements for submission of a request for an exception. As finalized in the FY 2017 IPPS/LTCH PPS final rule, if a hospital is granted an Extraordinary Circumstances Exception with respect to eCQM reporting for the applicable eCQM reporting period, the hospital would be excluded from the eCQM validation sample due to its inability to supply data for validation (81 FR 57181). We did not propose any changes to these policies in the proposed rule.

[1087] **Federal Register** unpublished display version available at: *https://www.federalregister.gov/public-inspection/2022-15372/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment*

F. Updates to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program is authorized by section 1866(k) of the Act and applies to hospitals described in section 1886(d)(1)(B)(v) (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs''). For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to all of the following final rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53555 through 53567).
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50286).
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723).
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193).
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425).
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41624).
- The CY 2019 OPPS/ASC final rule with comment period (83 FR 59149 through 59154).
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42509 through 42524).
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58959 through 58966).
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45426 through 45437).

We also refer readers to 42 CFR 412.23(f) and 412.124 for the PCHQR Program regulations.

2. Measure Retention and Removal Factors for the PCHQR Program

a. Current Measure Retention and Removal Factors

For a detailed discussion regarding our retention and removal factors, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57183), where we adopted policies for measure retention and removal, and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41611), where we updated our measure removal factors. We did not propose any changes to our measure retention policy. We describe our proposal to update our measure removal policy in the following section.

b. Adoption of a Patient Safety Exception to the Measure Removal Policy

To further align with the measure removal policies adopted in other quality programs such as the Hospital IQR Program (74 FR 43864), Hospital VBP Program (83 FR 41446), and HAC Reduction Program (84 FR 42404 to 42406), we proposed that if we believe continued use of a measure in the PCHQR Program raises specific patient safety concerns, we may promptly remove the measure from the program without rulemaking and notify hospitals and the public of the removal of the measure, along with the reasons for its removal through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet website. We would then provide notice of the removal in the **Federal Register**. In circumstances where we do not believe that continued use of a measure raises specific patient safety concerns, we would use the regular rulemaking process to remove a measure. We stated that the proposed policy mirrors that of the Hospital IQR Program, Hospital VBP Program, and HAC Reduction Program, and we continue to believe that a mechanism to immediately remove a quality measure that is causing specific and unintended patient harm aligns with our patient-centered focus.

We further proposed to add this patient safety exception to our regulations by revising 42 CFR 412.24(d)(3) to add a new paragraph (d)(3)(iii). We invited public comment on these proposals.

Comment: Commenters supported the proposal to adopt a patient safety exception to the measure removal policy and revise 42 CFR 412.24(d)(3) to add a new paragraph (d)(3)(iii).

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to adopt a patient safety exception to the measure removal policy and revise 42 CFR 412.24(d)(3) to add a new paragraph (d)(3)(iii) beginning in FY 2023.

3. Potential Adoption of Two National Healthcare Safety Network (NHSN) Measures—Request for Information

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28563), we sought comment on a potential future proposal to adopt the NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome measure and NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure into the PCHQR Program. We refer readers to section IX.E.9.a. of the preamble of the proposed rule, where we requested information on potentially adopting them for the Hospital IQR Program, and we noted that we are also considering proposing them for the HAC Reduction Program. With respect to the PCHQR Program, we stated that we were considering proposing these measures because cancer patients are often immunosuppressed and therefore more vulnerable to healthcare-associated infections (HAIs). We stated that we believed these measures will drive an increase in prevention practices, which may lead to a reduction in the number of HAI cases, morbidity, and mortality. We refer readers to section IX.E.9.a. of the preamble of this final rule for a discussion of the comments received regarding this cross-program RFI.

4. Summary of PCHQR Program Measures for the FY 2024 Program Year and Subsequent Years

Table IX.F.–01 summarizes the PCHQR Program measure set for the FY 2024 program year and subsequent years. We did not propose any changes to the PCHQR Program measure set.

TABLE IX.F.-01: FY 2024 PCHQR PROGRAM MEASURE SET AND SUBSEQUENT YEARS

Short Name	NQF Number	Measure Name
Safety and Healthcare-Associated Infection (HAI) Measures		
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	0139	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure
HCP	0431	Influenza Vaccination Coverage Among Healthcare Personnel
Colon and Abdominal Hysterectomy SSI	0753	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery]
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
COVID-19 HCP Vaccination	N/A	COVID-19 Vaccination Coverage Among HCP
Clinical Process/Oncology Care Measures		
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice
Intermediate Clinical Outcome Measures		
EOL-ICU	0213	Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life
EOL-3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days
Patient Engagement/Experience of Care Measure		
HCAHPS	0166	HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
N/A	3188	30-Day Unplanned Readmissions for Cancer Patients
N/A	N/A	Surgical Treatment Complications for Localized Prostate Cancer

5. Maintenance of Technical Specifications for Quality Measures

We maintain and periodically update technical specifications for the PCHQR Program measures. The specifications may be found on the QualityNet website at *https://qualitynet.cms.gov/pch*. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), where we adopted a policy to use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. We did not propose any changes to our processes for maintaining technical specifications for PCHQR Program measures.

6. Public Display Requirements

a. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review its data before they are made public. We are specifically required to report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished by PCHs on the CMS website.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191 through 57192), we finalized that although we would continue to use rulemaking to establish what year we first publicly report data on each measure, we would publish the data as soon as feasible during that year. We also stated that our intent is to make the data available on at least a yearly basis, and that the time period for PCHs to review their data before the data are made public would be approximately 30 days in length. We announce the exact data review and public reporting timeframes on a CMS website and our applicable Listservs. Currently, the PCHQR measures' performance data are made publicly available on the Provider Data Catalog available at *https://data.cms.gov/provider-data/*.

We recognize the importance of being transparent and keeping the public abreast of any changes that arise with the PCHQR Program measure set. As such, in this final rule, we are finalizing our proposals to begin public display of the four end-of-life measures with modification and the 30-Day Unplanned Readmissions for Cancer Patients measure.

b. Public Display of the End-of-Life (EOL) Measures

We proposed to begin public display of the EOL-Chemo, EOL-Hospice, EOL–ICU, and EOL–3DH measures (collectively, the ''EOL measures'') beginning with FY 2024 program year data. We adopted these measures for the PCHQR measure set beginning with FY 2020 program year data (82 FR 38414 through 38420). In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42523

through 42524), we finalized that we would confidentially report PCH performance on these measures to individual PCHs, and we indicated that we would propose to publicly display PCH performance on the measures after this initial confidential reporting period. We stated that we anticipated providing confidential reports on the data collected on the measures for the FY 2022 and FY 2023 program years, which correspond to data collected from July 1, 2019, to June 30, 2020 and July 1, 2020, to June 30, 2021, respectively, within calendar year 2022. We also stated that under our current policy, the measures are calculated on a yearly basis based on data collected from July 1 of the year 3 years prior to the program year to June 30 of the year 2 years prior to the program year. Therefore, we proposed to begin public reporting of these measures beginning with the FY 2024 program year data, which corresponds to data collected from July 1, 2021 through June 30, 2022. We stated that we would make these data publicly available following a 30-day period in which PCHs would have an opportunity to review the data. Public display would occur during the July 2023 refresh cycle or as soon as feasible thereafter. We further stated that we would announce the exact timeframe on a CMS website and our applicable listservs.

We invited public comment on the proposal to begin public display of the four EOL measures beginning with the FY 2024 program year data.

Comment: A few commenters supported the proposal to begin public display of the four EOL measures, stating that this public display will provide valuable information about hospital performance to patients. Another commenter specifically supported public display of the EOL-Chemo and EOL–ICU measures, stating that the data from these measures would complement the ADCC Serious Illness project.

Response: We thank the commenters for their support of publicly displaying the four EOL measures. We also thank the commenter who supported public display of the EOL-Chemo and EOL–ICU measures.

Comment: Several commenters requested that CMS delay public reporting of the EOL measures until hospitals can review their FY 2022 confidential reports, the release of which was delayed by one year.

Response: We thank the commenters for their feedback. The FY 2022 confidential feedback reports were made available to PCHs in June 2022. We anticipate the FY 2023 confidential reports will be made available to PCHs in August 2022 or as soon as feasible thereafter. We agree that the delay in releasing the FY 2022 and FY 2023 confidential feedback reports necessitates a delay in public reporting in order to provide PCHs with sufficient time to gain familiarity with the measure calculation and results. We believe a one-year delay, which is the minimum delay possible due to measure reporting timelines, will be sufficient to provide PCHs with additional time while balancing the importance of transparency of the EOL measure data.

Comment: Another commenter expressed concern about the lack of context for publicly displayed measure data such as individual patients' preferences and needs, which may lead to misrepresentation of the quality of cancer care.

Response: We thank the commenter for sharing their concern. The measure information will initially be available only via the Provider Data Catalog (PDC), and we are in the process of making this data available via Care Compare for public display. We would like to reiterate that PCHs will have a 30-day review period to confirm accuracy of the measure data before public display, and measures rates will be displayed with any appropriate context for ease of understanding the results.

After consideration of the public comments we received, we are finalizing our proposal to begin public reporting of the four EOL measures, with modification. Specifically, we are finalizing to begin public reporting beginning with FY 2025 program year data, which corresponds to data collected from July 1, 2022, through June 30, 2023, to provide hospitals with enough time to review their confidential reports. Public display will occur during the July 2024 refresh cycle or as soon as feasible thereafter. We will announce the exact timeframe on a CMS website and PCHQR Program listservs.

c. Public Display of the 30-Day Unplanned Readmissions for Cancer Patients Measure Beginning With the FY 2024 Program Year Data

We proposed to begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure beginning with FY 2024 program year data. We adopted this measure for the PCHQR measure set beginning with FY 2021 program year data (83 FR 41613 through 41616). In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42523 through 42524), we finalized that we would confidentially report this measure to individual PCHs, and we indicated that we would propose public display after this initial confidential reporting period. We provided confidential reports on the data collected on this measure for the FY 2022 program year in July 2021. In addition, we stated that we anticipated confidentially reporting data collected on the measure for the FY 2023 program year, which corresponds to data collected from October 1, 2020 to September 30, 2021, in July 2022.

Under our current policy, the measure is calculated on a yearly basis based on data collected from October 1 of the year 3 years prior to the program year to September 30 of the year 2 years prior to the program year. We proposed to begin public reporting of this measure beginning with the FY 2024 program year data, which corresponds to data collected from October 1, 2021 through September 30, 2022. We stated that we would make these data publicly available following a 30-day period in which PCHs would have an opportunity to review the data. Public display would occur during the October 2023 refresh cycle or as soon as feasible thereafter. We stated that we would announce the exact timeframe on a CMS website and our applicable listservs.

We invited public comment on the proposal to begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure beginning with the FY 2024 program year data.

Comment: Several commenters supported the proposal to begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure beginning with the FY 2024 program year data. A few commenters noted that that the FY 2021 confidential reports were reflective of measure specifications. A few commenters applauded CMS' early release of the confidential reports, allowing for proactive review prior to reporting periods. A commenter stated their belief that the measure will provide valuable information about hospital performance to patients.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure beginning with the FY 2024 program year data.

d. Summary of Previously Finalized and Newly Finalized Public Display Requirements for the PCHQR Program

Our previously finalized and newly finalized public display requirements for the PCHQR Program measures are shown in the following Table IX.F.–02:

TABLE IX.F-02: PREVIOUSLY FINALIZED AND NEWLY FINALIZED PUBLIC DISPLAY REQUIREMENTS FOR THE PCHQR PROGRAM

Summary of Previously Finalized and Newly Finalized Public Display Requirements	
Measures	**Public Reporting**
• HCAHPS (NQF #0166) • Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383)*	2016 and subsequent years
• American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (NQF #1716) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) • National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)	2019 and subsequent years
• COVID-19 Vaccination Coverage Among Healthcare Personnel	October 2022 and subsequent years
• Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	April 2020 and subsequent years
• CAUTI (NQF #0138) • CLABSI (NQF #0139)	Deferred until October 2022
• Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210)** • Proportion of Patients Who Died from Cancer Not Admitted to Hospice (NQF #0215)** • Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213)** • Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (NQF #0216)**	July 2024 or as soon as feasible thereafter
• 30-day Unplanned Readmissions for Cancer Patients (NQF #3188)***	October 2023 or as soon as feasible thereafter

**Measure finalized for removal, beginning with the FY 2024 program year.*
***Measure finalized for public display beginning with FY 2025 program year data.*
****Measure finalized for public display beginning with FY 2024 program year data.*

7. Form, Manner, and Timing of Data Submissions

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53567) for our previously finalized procedural requirements for the PCHQR Program. Data submission requirements and deadlines for the PCHQR Program are posted on the QualityNet website. We did not propose any updates to our previously finalized data submission requirements and deadlines.

8. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624), for a discussion of the Extraordinary Circumstances Exceptions (ECE) policy under the PCHQR Program. We did not propose any changes to this policy.

G. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as Long-Term Care Hospitals (LTCHs). Section 1886(m)(5)(C) of the Act requires LTCHs to submit to the Secretary quality measure data specified under section 1886(m)(5)(D) in a form and manner, and at a time, specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act, resource use or other measures under section 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. LTCHs must submit the data required under section 1886(m)(5)(F) of the Act in the form and manner, and at the time, specified by the Secretary. Under the LTCH QRP, the Secretary must reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. For more information on the background for the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51744), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50853), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49725), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57193), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38425 through 38426), the FY 2019 IPPS/LTCH PPS

final rule (83 FR 41624 through 41634), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42524 through 42591), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45438 through 45446). For more information on the requirements under the LTCH QRP, we refer readers to 42 CFR 412.560.

2. General Considerations Used for the Selection of Quality Measures for the LTCH QRP

For a detailed discussion of the considerations we historically use for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728).

3. Quality Measures Currently Adopted for the FY 2023 LTCH QRP

The LTCH QRP currently has 18 measures for the FY 2023 LTCH QRP, which are set out in the following Table IX.G.-01. For a discussion of the factors used to evaluate whether a measure should be removed from the LTCH QRP, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634) and to the regulations at 42 CFR 412.560(b)(3).

TABLE IX.G.-01. QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2023 LTCH QRP

Short Name	Measure Name & Data Source
LTCH CARE Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)
Functional Assessment	Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
Application of Functional Assessment/ Care Plan	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support (NQF #2632)
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
Ventilator Liberation	Ventilator Liberation Rate
TOH–Provider*	Transfer of Health Information to the Provider Post-Acute Care (PAC)
TOH–Patient*	Transfer of Health Information to the Patient Post-Acute Care (PAC)
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
CLABSI	National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)
HCP COVID-19 Vaccine	COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) (NQF #3562)
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) (NQF #3480)
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)

*In response to the COVID-19 public health emergency (PHE), we released an interim final rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the Transfer of Health Information measures. The compliance date for the collection and reporting of the Transfer of Health Information measures was revised to October 1, 2022 in the CY 2022 Home Health Prospective Payment System Rate Update final rule (86 FR 62386 through 62390).

There were no proposals in the proposed rule for new measures for the LTCH QRP.

4. LTCH QRP Quality Measure Concepts Under Consideration for Future Years: Request for Information (RFI) Included in the FY 2023 IPPS/LTCH PPS Proposed Rule

In the FY 2023 IPPS/LTCH PPS proposed rule, we sought input on the importance, relevance, and applicability of the concepts under consideration listed in Table IX.G.-02 for future years in the LTCH QRP. More specifically, we sought input on a cross-setting functional measure that would incorporate the domains of self-care and mobility. Our measure development contractor for the cross-setting functional outcome measure convened a Technical Expert Panel (TEP) on June 15 and June 16, 2021 to obtain expert input on the development of a functional outcome measure for PAC. During this meeting, the possibility of creating one measure to capture both self-care and mobility was discussed. We also sought input on measures of health equity, such as structural measures that assess an organization's leadership in advancing equity goals or assess progress towards achieving equity priorities. Finally, we sought input on the value of a COVID–19 Vaccination Coverage measure that would assess whether LTCH patients were up to date on their COVID–19 vaccine.

TABLE IX.G.-02: FUTURE MEASURE CONCEPTS UNDER CONSIDERATION FOR THE LTCH QRP

Quality Measure Concepts
Cross-Setting Function
Health Equity Measures
PAC - COVID-19 Vaccination Coverage among Patients

Comment: Commenters were generally supportive of a cross-setting functional outcome measure, although some commenters expressed concern over the potential burden of collecting additional information. Some commenters emphasized that the measure should provide meaningful information to patients, caregivers, discharge planners, providers, and payers, and noted that LTCH patients often have different levels of acuity and treatment needs so a future measure must be able to differentiate LTCHs from one another. Two commenters stated that since LTCH patients have different levels of acuity and treatment needs, it may make comparisons to other ''PAC'' settings not appropriate, even when risk adjustment is used. These commenters urged CMS to consider measures that incorporate improvement in function, but also recognize that some patients may not demonstrate improvement due to their medical condition(s). A commenter stated they preferred separate quality measures for self-care and mobility, but would support the initial use of a composite measure reflecting both self-care and mobility function. Another commenter opposed the inclusion of a measure that was based on provider-reported assessment data.

We received mixed comments regarding a health equity measure in the LTCH QRP. Two commenters were concerned with how accurate a health equity measure could be for LTCHs given their small sample sizes, and whether LTCHs would be able to meaningfully improve a measure of health equity. Other commenters were strongly supportive of including health equity measures in the LTCH QRP in a future year.

Commenters stated they understood why CMS was considering a COVID–19 Vaccination Coverage among Patients measure, but noted CMS should postpone considering this measure since the definition of ''fully vaccinated'' is evolving.

We also received comments suggesting CMS consider other measure concepts for the LTCH QRP, including malnutrition and patient-reported outcomes. A commenter urged CMS to consider a measure of malnutrition screening since malnutrition is a risk factor for several clinical events, including falls and delayed healing. Another commenter suggested measures of patient experience, patient and workforce safety and reliability, clinical quality, and caregiver engagement that are evidence-based, targeted, and meaningful to patients and caregivers.

Response: As discussed in the proposed rule, we are not responding to specific comments submitted in response to this RFI in this final rule, but we intend to use this input to inform our future measure development efforts.

5. Inclusion of the National Healthcare Safety Network (NHSN) Healthcare-Associated *Clostridioides difficile* Infection Outcome Measure in the LTCH QRP—Request for Information (RFI) Included in the FY 2023 IPPS/LTCH PPS Proposed Rule

a. Solicitation of Public Comment

In the FY 2023 IPPS/LTCH PPS proposed rule, we requested stakeholder input on the potential electronic submission of quality data from LTCHs via their electronic health records (EHRs) under the LTCH QRP. We specifically sought public comment on the future inclusion of the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure (HA–CDI) (MUC2021–098) as a digital quality measure in the LTCH QRP.

Specifically, we sought public comment on the following:

- Would you support utilizing LTCH EHRs as the mechanism of data collection and submission for LTCH QRP measures?
- Would your EHR support exposing data via HL7 Fast Healthcare Interoperability Resources (FHIR) to a locally installed Measure Calculation Tool (MCT)? For LTCHs using certified health IT systems, how can existing certification criteria under the Office of the National Coordinator (ONC) Health Information Technology (IT) Certification Program support reporting of these data? What updates, if any, to the Certification Program would be needed to better support capture and submission of these data?
- Is a transition period between the current method of data submission and

an electronic submission method necessary? If so, how long of a transition would be necessary, and what specific factors are relevant in determining the length of any transition?

• Would vendors, including those that service LTCHs, be interested in or willing to participate in pilots or voluntary electronic submission of quality data?

• Do LTCHs anticipate challenges, other than the adoption of EHR, to adopting the NHSN HA–CDI measure, and if so, what are potential solutions for those challenges?

We received several comments on this RFI, which are summarized in this section of this document:

Comment: Commenters were mixed in their support of utilizing LTCH EHRs as the mechanism for data collection and submission for LTCH QRP measures. While all commenters supported the concept of reducing provider burden through using fully digital measures, commenters did note several barriers. A commenter noted that the transition would take time and staffing hours away from other clinical initiatives. Most commenters raised concerns about the cost associated with LTCHs t adopting EHR systems that are equipped to collect and exchange digital quality measure (dQM) data. They stated that EHR adoption has been slower and less uniform than it was in acute care hospitals, due to the lack of incentive payments available to LTCHs. They urged CMS to provide incentive payments to LTCHs as they did for acute care hospitals through the Health Information Technology for Economic and Clinical Health (HITECH) Act prior to requiring LTCHs' transition to dQMs.

A commenter stated that their EHR would support exposing data via HL7 FHIR to a locally installed MCT. Another commenter stated they had concerns about the definition of treatment, as well as potential gaming of the measure that could lead to the untended consequences of overuse of antimicrobials or the undertreatment of patients with CDI. This commenter also suggested CMS to work with CMS to determine whether risk adjustment based on hospital characteristics is needed. Finally, they cautioned that electronic reporting is evolving and they requested CMS work with the Office of the National Coordinator for Health Information Technology (ONC) and other EHR vendors to fully integrate electronic reporting options before implementation.

Commenters universally agreed that a transition period would be necessary to set up processes capable of electronic submission of data. They stressed that LTCHs would need significant lead time to ensure they could be compliant with new digital reporting requirements, and estimated it would take a minimum of 2 years to transition to digital reporting. Another commenter stated that a switch to dQMs would involve a number of different workflows, and that sufficient testing would be important since LTCHs could be penalized 2% for an entire year if they were found non-compliant.

A commenter urged CMS to allow LTCH provider organizations, in addition to vendors, to participate in any pilots or testing of dQMs before implementation.

Response: We will consider all input as we develop future regulatory proposals. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

6. Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS

a. Solicitation of Public Comment

The goal of this request for information was to describe some key principles and approaches that we will consider when advancing the use of quality measure development and stratification to address healthcare disparities and advance health equity across our programs.

We invited general comments on the principles and approaches described previously in this section of the rule, as well as additional thoughts about disparity measurement guidelines suitable for overarching consideration across CMS's QRP programs. Specifically, we invited comment on the following:

• *Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs*

++ The use of the within- and between-hospital disparity methods in LTCHs to present stratified measure results.

++ The use of decomposition approaches to explain possible causes of measure performance disparities.

++ Alternative methods to identify disparities and the drivers of disparities.

• *Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting*

++ Principles to consider for prioritization of health equity measures and measures for disparity reporting, including prioritizing stratification for validated clinical quality measures, those measures with established disparities in care, measures that have adequate sample size and representation among healthcare providers and outcomes, and measures of appropriate access and care.

• *Principles for Social Risk Factor (SRF) and Demographic Data Selection and Use*

++ Principles to be considered for the selection of SRFs and demographic data for use in collecting disparity data including the importance of expanding variables used in measure stratification to consider a wide range of SRFs, demographic variables, and other markers of historic disadvantage. In the absence of patient-reported data we will consider use of administrative data, area-based indicators, and imputed variables as appropriate.

• *Identification of Meaningful Performance Differences*

++ Ways that meaningful difference in disparity results should be considered.

• *Guiding Principles for Reporting Disparity Measures*

++ Guiding principles for the use and application of the results of disparity measurement.

• *Measures Related to Health Equity*

++ The usefulness of a Health Equity Summary Score (HESS) for LTCHs, both in terms of provider actionability to improve health equity, and in terms of whether this information would support Care Compare website users in making informed healthcare decisions.

++ The potential for a structural measure assessing an LTCH's commitment to health equity, the specific domains that should be captured, and options for reporting these data in a manner that would minimize burden.

++ Options to collect facility-level information that could be used to support the calculation of a structural measure of health equity.

++ Other options for measures that address health equity.

We received several comments on the RFI for Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs. While we will not be responding to specific comments submitted in response to this RFI, the following is a summary of some comments received:

Comment: Many commenters provided feedback on the use of the within-provider and between provider disparity methods to present stratified measure results. Overall, comments were generally supportive of implementing both methods in order to provide a more complete picture of the

quality of care provided to beneficiaries with SRFs.

In terms of specific feedback related to the implementation of these stratification approaches, a few commenters stated CMS should prioritize expansion of the within-provider method over the between-provider method due to the fact that the latter method might provide an incomplete picture of disparity and would not inform a LTCH's an understanding of its own performance. Other commenters suggested CMS consider using peer groups for between-provider comparisons, such as peer LTCHs identified based patient demographic profile, geographic location, or bed size. A commenter noted concern that within-provider methods may place excessive responsibility on providers to mitigate the disparities without providing the resources to take action. Another commenter stated the feedback would be more actionable and useful if the results included information beyond what hospitals already collect. Finally, a commenter recommended feedback methods should be carefully considered for each type of measure, and specifically pointed out that patient experience measures may not be appropriate to compare between subgroups since it could lend itself to misinterpretation and labeling of certain subgroups of patients.

Several commenters responded to the disparity decomposition approach presented in the proposed rule. A commenter noted the decomposition approach described could be a promising method to identify specific drivers of performance disparities, which would increase the actionability of stratified measure information while adding no additional burden to providers. Other commenters supported the method, but a commenter did caution that LTCHs would be limited in their ability to address patients' needs while under their care. A few commenters opposed the use of decomposition techniques, citing their concern that if statistical methods are poorly chosen, some LTCHs may be labeled discriminatory unintentionally, causing harm to beneficiaries, providers and the Medicare program.

Commenters were overwhelmingly supportive of prioritizing existing quality measures for disparity reporting, and most commenters were also supportive of prioritizing measures with identified disparities in treatment or outcomes, or conditions that have highly disproportionate prevalence in certain populations. Many commenters stated CMS should focus on: (1) outcome measures over process measures; (2) use existing collected patient data and prevent additional reporting burdens on providers; and (3) have a meaningful and quantifiable impact on overall patient health and system cost. For those reasons, these commenters suggested measures such as hospital readmissions, mortality associated with certain health conditions, and potentially avoidable events. Support for prioritizing measures with adequate sample sizes and measures that seek to determine patient access to care and the appropriate use of care were suggested by many commenters as well.

Commenter also suggested additional guiding principles. A commenter recommended the measures should have essential characteristics such as being data-driven, actionable, feasible, have utility and be constructed such that providers have prompt feedback. Another commenter suggested CMS should focus on the areas of clinical quality, clinical safety and patient experience, while still another stressed alignment with other programs and agencies, where possible and appropriate.

We received a number of other comments on the guiding principles for selecting and prioritizing measures for disparity reporting. A commenter suggested the only criteria that should be used is whether the measure highlights disparities in care. Another commenter requested CMS clarify how it defines ''industry standards for measure reliability and validity.'' Finally, another commenter cautioned CMS against using this information to single out healthcare providers and take punitive action against them.

A number of commenters provider feedback on considerations for the selection of SRFs and demographic data for use in collecting disparity data. A majority of commenters supported using race and ethnicity, although a commenter recommended using any SRFs other than dual eligibility, race and ethnicity. Several commenters suggested using disability status, and two of these commenters also suggested using primary language. Other data points were suggested, including sexual orientation, gender identity, age, and health literacy. Finally, a commenter recommended CMS use a standard definition of the term ''disparity'' that can be used as a measurable benchmark across programs.

The feedback received on methods for determining meaningful performance differences in disparity results was mixed. First, we summarize the comments regarding the four possible reporting approaches discussed in section IX.E.6.1.4 the proposed rule, and then summarize comments recommending other approaches.

While several commenters were generally supportive of benchmarking, one provider stated the data was too limited at the current time to apply benchmarks and another commenter noted it could mask local or regional differences in patient populations and thus inadvertently penalize providers. A commenter provided feedback specific to using statistical differences to identifying meaningful performance differences, and the commenter recommended that if this approach were used the measure, along with an estimate of its variability, such as a confidence interval, be displayed with it to aid in its interpretation. Several commenters did not support ranked orderings and percentiles and cautioned they could lead to significant unintended consequences, and two of these commenters noted that they do not necessarily translate to meaningful clinical differences. Finally we received two comments supporting the use of defined thresholds, such as fixed intervals of results of disparity reporting, but several commenters did not support this method. The most notable reason given was their concern this method created an artificial cutoff where small performance differences are either acceptable or unacceptable, and it could result in inappropriately characterizing some LTCHs as practicing discrimination. We also received one comment recommending CMS use a combination of peer group benchmarking and statistical significance.

Commenters also recommended other approaches. A commenter recommended CMS conduct analyses to compare the results of different methods and publish the results of these analyses for stakeholder review and public comment. Other commenters urged CMS not to apply a one-size-fits-all approach, and suggested CMS may need to tailor the approaches to the individual patient populations and quality program. A few commenters noted that before any analyses are completed, CMS will need to define a statistically acceptable minimum threshold for determining a disparity exists as well as a high reliability standard for determining the minimum number of observations required for a provider's performance to be stratified and reported.

Several commenters responded to CMS' request for information about measures CMS could develop to assess and encourage health equity, including

comments regarding the usefulness and actionability of HESS and the potential for a structural measure to assess SNFs' commitment to health equity. We first summarize the comments regarding the HESS, then summarize comments related to a structural measure to assess commitment to equity.

Several commenters specifically addressed the HESS. A commenter simply encouraged CMS to clarify that the HESS would assess individual SNFs as a whole, as opposed to the individual clinicians within each SNF. The two remaining commenters either supported or appreciated the HESS score in concept, but raised several concerns pertaining to technical barriers, ambiguity in the methodology, and usability of the measure. In terms of technical concerns, a commenter noted that the availability of a standardized set of demographic data elements must be available for each patient, and stated that demographic data elements are not yet standardized across healthcare setting and organizations. Regarding methodological concerns, a commenter questioned how one could combine within-facility disparities and disparities across facilities into a single summary score in a manner that would accurately reflect both the individual and potentially independent factors that may result in these different types of disparities. Other commenters raised similar concerns about the usability the HESS, primarily stemming from the extent to which disparities across multiple measures and SRFs are aggregated into a single score. Specifically, commenters noted that one SRF included in the HESS could mask the effects of other SRFs, which could potentially lead to misinterpretation of the overall score. Another commenter stated the measure was vague and therefore would not be actionable by their members or meaningful to the public.

Several commenters addressed the potential for a structural measures to assess health equity. A commenter stated that a structural measure would have a low level of burden, while signaling to the LTCH community the importance of focusing improvement efforts on health equity and prompting the healthcare organization to consider their ongoing or needed efforts to address each domain. Another commenter noted that the development of a structural measure to assess engagement and commitment of leadership toward advancing health equity should be included as one of several guiding principles to address health disparities and achieve health equity. Another commenter cautioned against the development of structural measures, suggesting that such measures would only demonstrate whether an organization is ''good at checking the box'' for the purpose of meeting the requirements of a measure.

Response: We appreciate all of the comments and interest in this important topic. Public input is very valuable in the continuing development of CMS's health equity quality measurement efforts and broader commitment to health equity, a key pillar of our strategic vision as well as a core agency function. Thus, we will continue to take all concerns, comments, and suggestions into account for future development and expansion of policies to advance health equity across the LTCH QRP, including by supporting LTCHs in their efforts to ensure equity for all of their patients, and to identify opportunities for improvements in health outcomes. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

7. Form, Manner, and Timing of Data Submission Under the LTCH QRP

We refer readers to the regulatory text at 42 CFR 412.560(b) for information regarding the current policies for reporting LTCH QRP data.

For more details about the required reporting periods of measures or standardized patient assessment data during the first and subsequent years upon adoption, please refer to the FY 2020 IPPS/LTCH PPS final rule (84 FR 24588 through 24590).

We did not propose any new policies regarding the form, manner, and timing of data submission under the LTCH QRP.

8. Policies Regarding Public Display of Measure Data for the LTCH QRP

We did not propose any new policies regarding the public display of LTCH QRP measure data.

H. Changes to the Medicare Promoting Interoperability Program

1. Statutory Authority for the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs)

The Health Information Technology for Economic and Clinical Health Act (HITECH Act) (Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), together with Title XIII of Division A of the ARRA) authorized incentive payments under Medicare and Medicaid, as well as downward payment adjustments under Medicare, for the adoption and meaningful use of certified electronic health record technology (CEHRT). Incentive payments under Medicare were available to eligible hospitals and CAHs for certain payment years (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrated meaningful use of CEHRT, which included reporting on clinical quality measures using CEHRT. In accordance with the timeframe set forth in the statute, these incentive payments under Medicare are no longer available. Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act authorize downward payment adjustments under Medicare, beginning with Federal fiscal year (FY) 2015 (and beginning with FY 2022 for subsection (d) Puerto Rico hospitals), for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for certain associated electronic health record (EHR) reporting periods.

2. EHR Reporting Period

Under the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4, for eligible hospitals and CAHs that are new or returning participants in the Medicare Promoting Interoperability Program, the EHR reporting period in calendar year (CY) 2023 is a minimum of any continuous 90-day period within CY 2023, and the EHR reporting period in CY 2024 is a minimum of any continuous 180-day period within CY 2024. For more information, we refer readers to the discussion in the FY 2022 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital (IPPS/LTCH) Prospective Payment System (PPS) final rule (86 FR 45460 through 45462).

a. CEHRT Requirements

The Promoting Interoperability Program and the Quality Payment Program (QPP) require the use of CEHRT as defined at 42 CFR 495.4 and 414.1305, respectively. Since 2019, in general, this has consisted of EHR technology (which could include multiple technologies) certified under the Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology (IT) Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition.

The ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (also referred to as the ''ONC 21st Century Cures Act final rule''), published in the May 1, 2020, **Federal Register** (85 FR 25642 through 25961), finalized a number of updates to the 2015 Edition of health IT certification criteria (also referred to as the 2015 Edition Cures Update) and introduced new 2015 Edition certification criteria. In connection with these updates, ONC also finalized that health IT developers have 24 months from the publication date of the final rule (until May 2, 2022) to make technology available that is certified to the updated, or new criteria. In response to additional calls for flexibility in response to the Public Health Emergency (PHE) for COVID–19, ONC published an interim final rule with comment period on November 4, 2020 entitled, ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereinafter the ''ONC interim final rule'') (85 FR 70064). In this interim final rule, ONC finalized extended compliance dates for certain 2015 Edition certification criteria. Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication date of the final rule to make technology certified to new or updated criteria available, ONC extended the timeline until December 31, 2022 (and until December 31, 2023, for 45 CFR 170.315(b)(10), ''electronic health information (EHI) export'').

In the CY 2021 Physician Fee Schedule (PFS) final rule (85 FR 84815 through 84825), we finalized that the technology used by health care providers to satisfy the definitions of CEHRT at 42 CFR 495.4 and 414.1305 must be certified under the ONC Health IT Certification Program, in accordance with the updated 2015 Edition certification criteria as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). We further finalized aligning the transition period during which health care providers participating in the Promoting Interoperability Program or QPP may use technology certified to either the existing or updated 2015 Edition certification criteria, with the December 31, 2022, date established in the ONC interim final rule for health IT developers to make updated certified health IT available. After this date, health care providers will be required to use only certified technology updated to the 2015 Edition Cures Update for an EHR reporting period or performance period in CY 2023. We did not propose any changes to this policy.

We remind readers that health care providers would not be required to demonstrate that they are using updated technology to meet the CEHRT definitions immediately upon the transition date of December 31, 2022. In accordance with the EHR reporting period and performance period established for the Promoting Interoperability Program and the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category, participants are only required to use technology meeting the CEHRT definitions during a self-selected EHR reporting period or performance period of a minimum of any consecutive 90 days in CY 2023, including the final 90 days of 2023 (86 FR 45460 through 45462 and 86 FR 65466, respectively). The eligible hospital, CAH, or MIPS eligible clinician is not required to demonstrate meaningful use of technology meeting the 2015 Edition Cures Update until the EHR reporting period or performance period they have selected.

3. Electronic Prescribing Objective: Changes to the Query of Prescription Drug Monitoring Program Measure and Technical Update to the E-Prescribing Measure

a. Query of Prescription Drug Monitoring Program Measure Background

We have adopted the Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing Objective. For background on this measure, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41648 through 41653), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42595), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45462 through 45464). In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969), we finalized that the Query of PDMP measure will remain optional and eligible for 5 bonus points for EHR reporting periods in CY 2021. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45464), we finalized that the Query of PDMP measure will remain optional and increased the eligible bonus points to 10 points for CY 2022.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42596), FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969), and FY 2022 IPPS/LTCH PPS final rule (86 FR 45462 through 45464), we described the concern expressed by interested parties who believed it was premature for the Medicare Promoting Interoperability Program to require the Query of PDMP measure and to score it based on performance. We heard extensive feedback from EHR developers that effectively incorporating the ability to count the number of PDMP queries in the EHR would require more robust measurement specifications. These interested parties stated that EHR developers may face significant cost burdens if they fully develop numerator and denominator calculations and are then required to change the specification at a later date. Interested parties stated that the costs of additional development would likely be passed on to health care providers without additional benefit, as this development would be solely for the purpose of calculating the measure, rather than furthering the clinical goal of the measure. While we recognize that a numerator/denominator-based measure remains challenging, we also note (as discussed in more detail later in this section of the final rule) that the widespread availability of PDMPs across the country, and recent progress toward solutions for connecting PDMPs with provider EHR systems, has made use of PDMPs feasible through a wide variety of approaches.

b. Current Status of PDMP Adoption

Today, all 50 states and several localities host PDMPs.[1088] The final state to establish a PDMP, the state of Missouri, passed legislation to address this issue in 2021, and is currently working to make its PDMP operational. A 2021 American Medical Association report found that physicians and others used state PDMPs more than 910 million times in 2020.[1089] An assessment of PDMPs conducted by the PDMP Training and Technical Assistance Center (TTAC) at the Institute for Intergovernmental Research (IIR) found an increase in the number of PDMPs that are integrated with Health Information Exchanges (HIEs), EHRs, and/or Pharmacy Dispensing Systems (PDSs), with 44 PDMPs integrated in

[1088] Prescription Drug Monitoring Program Training and Technical Assistance Center, PDMP Policies and Capabilities: Results From 2021 State Assessment, September 2021, *https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202021%20Assessment%20Results_20210921.pdf.*

[1089] American Medical Association, 2021 Overdose Epidemic Report, *https://www.ama-assn.org/system/files/ama-overdose-epidemic-report.pdf.*

2021 reflecting an increase from 28 PDMPs with at least one type of integration in 2017. We refer readers to Table IX.H.-01. for the report's findings on the type of integration and the number of PDMPs that have implemented that type of integration in 2021.

TABLE IX.H.-01.: PDMP INTEGRATION – TYPE AND NUMBER OF PDMPS[1090]

Type of Integration	# of PDMPs
EHR and PDS	35
HIE and EHR	20
HIE, EHR, and PDS	18
EHR only	5
HIE only	1
PDS only	1

Moreover, a number of enhancements to PDMPs and related initiatives are occurring across the country, including enhancements to RxCheck, which is a free, federally supported interstate exchange hub for PDMP data. RxCheck is connected to 50 out of 54 PDMPs in states and territories and does not require providers to pay to have access to PDMP data from other states and territories that are also live on RxCheck. The CDC, in partnership with ONC and other industry stakeholders, have been working to connect RxCheck to the eHealth Exchange as an alternative pathway for providers to conduct interstate queries of patient medication histories. The goal of the project is to allow any health care provider who is live on the eHealth Exchange to use that existing connection to query a patient's record through the RxCheck Hub, which routes the query to individual State PDMPs that are also live on RxCheck. This solution enables health care providers to query PDMPs via existing connections to health information exchange networks. Most states use either RxCheck or Prescription Monitoring Program (PMP) InterConnect or both to facilitate the sharing of PDMP information between states, allowing health care providers to query other states' PDMP.[1091]

We also note that the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115–271), enacted in 2018, has focused on ways to address the nation's opioid epidemic. The SUPPORT for Patients and Communities Act included new requirements for PDMP enhancement and integration, to help reduce opioid misuse and overprescribing and promote the effective prevention and treatment of opioid use disorder beginning in October of 2021. Enhanced Federal matching funds were available to states to support related PDMP design, development, and implementation activities during fiscal years 2019 and 2020.

c. Changes to the Query of PDMP Measure and Related Policies

(1) Changes to the Query of PDMP Measure Description

The description of the Query of PDMP measure provides that for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law (42 CFR 495.24(e)(5)(iii)(B)). In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28579), beginning with the EHR reporting period in CY 2023, we proposed to require the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. We also noted that should we finalize our proposal to require the Query of PDMP measure beginning with the EHR reporting period in CY 2023, we proposed two exclusions beginning with the EHR reporting period in CY 2023: (1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include drugs from Schedules II, III, and IV, and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and (2) any eligible hospital or CAH that cannot report on this measure in accordance with applicable law (87 FR 28581). We also noted in the FY 2023 IPPS/LTCH PPS proposed rule that should we finalize the proposals to require the Query of PDMP measure and the associated exclusions, we believe the inclusion of the phrase ''except where prohibited and in accordance with applicable law'' in the description of the Query of PDMP measure and the inclusion of the phrase ''in accordance with applicable law'' in the second proposed exclusion for the Query of PDMP measure would be duplicative and potentially cause confusion (87 FR 28578). Therefore, we proposed to remove the phrase ''except where prohibited and in accordance with applicable law'' from the description of the Query of PDMP measure should our proposals to require the Query of PDMP measure and the associated exclusions be finalized. For additional information on proposed changes to the Query of PDMP measure, we referred readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28580).

We also stated in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28579) that should our proposal to remove associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program not be finalized, we propose to update the regulatory text to reflect these proposed changes at 42 CFR 495.24(e)(5). We invited public comment on these proposals.

Comment: A few commenters expressed support for our proposal to change the Query of PDMP measure description.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to change the

[1090] PDMP Policies and Capabilities: Results From 2021 State Assessment, September 2021, *https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202021%20Assessment%20Results_20210921.pdf*.

[1091] Government Accountability Office. GAO–21–22, PRESCRIPTION DRUG MONITORING PROGRAMS: Views on Usefulness and Challenges of Programs.

Query of PDMP measure description to remove the phrase ''except where prohibited and in accordance with applicable law''; we refer the reader to section IX.H.3.c.(3) for the finalized measure description. In section IX.H.8. of this final rule, we are finalizing our proposal to remove the associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program, and therefore, we will not be updating 42 CFR 495.24(e)(5) with our finalized changes to the Query of PDMP measure description.

(2) Changes To Require the Query of PDMP Measure

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45462), we noted that the decision to maintain the Query of PDMP as an optional measure for EHR reporting periods in CY 2022 considered the current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act, our ongoing review of alternative measure approaches, and interested party concerns about the current readiness across states for implementation of the existing measure. We also noted that this measure can play an important role in helping health care providers to improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions (86 FR 45463); maintaining it as an optional measure with bonus points signals to the hospital and vendor community that this is an important measure which can help spur development and innovation to reduce barriers and challenges (86 FR 45463).

We continue to believe that PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Querying the PDMP is important for tracking dispensed controlled substances and improving prescribing practices. Efforts to expand the use of PDMPs and integrate PMDPs with health information technology systems are supported by Federal agencies including ONC, the Centers for Disease Control and Prevention (CDC), the Department of Justice (DOJ), and the Substance Abuse and Mental Health Services Administration (SAMHSA). The Query of PDMP measure offers a way to reward health care providers who participate in current PDMP initiatives that are supported by Federal partners.

While work continues to improve standardized approaches to PDMP and EHR interoperability, we believe that it is feasible at this time to require health care providers to report the current Query of PDMP measure requiring a ''yes/no'' response. Given our policies for the Query of PDMP measure that included increasing the eligible bonus points to reward eligible hospitals and CAHs that could report the measure, as well as the recent progress in the availability of PDMPs in all fifty states, and solutions which support accessibility of PDMPs to health care providers, we believe eligible hospitals and CAHs have had time to grow familiar with what this measure requires of them, even as technical approaches to the use of PDMPs continue to advance. By requiring a ''yes/no'' response the current measure allows health care providers to use a variety of technical solutions to conduct a query of the PDMP and receive credit for the measure.

Therefore, beginning with the EHR reporting period in CY 2023, we proposed to require the current Query of PDMP measure requiring a ''yes/no'' response for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. We stated that we would maintain the associated points at 10 points and referred readers to section IX.H.6. of the proposed rule for a discussion of our scoring methodology and proposed concurrent changes. As a result of this proposal, the maximum total points available for the Electronic Prescribing Objective would remain at 20 points for EHR reporting periods in CY 2023. We also stated in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28579) that should our proposal to remove associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program not be finalized, we propose to update the regulatory text to reflect these proposed changes at 42 CFR 495.24(e)(5)(iii)(B).

We invited public comment on these proposals.

Comment: Many commenters expressed support for requiring the Query of PDMP measure because it remains a ''yes/no'' attestation-based measure; they noted that it allows for use of a variety of technical solutions to report the measure, and includes exclusions. Several commenters supported requiring the measure because querying a PDMP is critical to understanding a patient's medication history to inform effective, quality care, particularly when Schedule II opioids and Schedules III and IV drugs are prescribed and dispensed. They further stated that it is important for future public health initiatives and drug abuse prevention efforts.

Response: We would like to thank the commenters for their support. We agree that the Query of PDMP measure is an important tool for clinicians, and for improving prescribing practices geared towards overall patient safety.

Comment: Several commenters expressed their support stating that eligible hospitals and CAHs have had ample time to prepare for this change. For eligible hospitals and CAHs with continued challenges, a commenter shared that there are technological solutions available to make this requirement feasible. Last, commenters shared that the benefits of the measure outweigh concerns with implementation of improved systems to support access to PDMP data health IT system design, and that requiring the measure will continue to promote data exchange and more advanced EHR workflows.

Response: We appreciate the commenters' support for requiring the Query of PDMP measure. We agree that eligible hospitals and CAHs have had ample time to prepare for this requirement, and have had time to grow familiar with what this measure requires of them. As states continue to improve the accessibility of PDMPs through technical advances, we believe eligible hospitals and CAHs have an increasing number of solutions available to effectively query PDMPs.

Comment: Several commenters offered suggestions and recommendations for our consideration. A commenter recommended that CMS ensure that requiring the Query of PDMP measure would not create a barrier for clinicians appropriately prescribing opioids for patients. Another commenter recommended that CMS consider accounting for state laws that already require PDMP queries, and adjusting for known challenges, including state variability of PDMP requirements and processes and the availability of interstate data. A commenter recommended that CMS require States to work with EHR vendors to continue the integration process, thereby improving clinician workflow. A commenter recommended that CMS monitor the ability of CAHs and small rural hospitals to comply with the Query of PDMP measure and provide flexibility, support and technical assistance if disparities in capacity and ability to use IT systems are identified.

Response: We appreciate the commenters' support, including their

recommendations for our proposal. We agree it is important that the measure not create barriers for appropriate prescribing or create additional administrative burden, and believe that maintaining the measure as requiring a ''yes/no'' response allows eligible hospitals and CAHs to report while minimizing burden. Regarding the recommendation that CMS require states to work with EHR vendors and continuously monitor for known challenges, we thank commenters for this suggestion. CMS maintains communication with ONC, and together, we assess and monitor challenges that eligible hospitals and CAHs face with vendors and state-specific PDMPs. We appreciate commenters' concerns about the impact of requiring the Query of PDMP measure on CAHs and small rural hospitals. The Query of PDMP measure requires a ''yes/no'' response, and we believe this helps to minimize potential burden for small rural hospitals. We also refer readers to the finalized measure description for the Query of PDMP measure of this final rule at section IX.H.3.c.(3), where we state that we require a minimum of ''at least one'' query of the PDMP and that no maximum or suggested number of queries have been established. Last, CMS, as well as other HHS agencies, are supporting a number of initiatives to enable better integration between PDMPs and health IT systems used by health care providers. We refer readers to the FY 2023 IPPS/LTCH PPS proposed rule for further discussion (87 FR 28577 through 28578).

Comment: A few commenters expressed support for making the Query of PDMP measure required, so long as it is delayed until CY 2024. A few commenters have requested a delay in requiring the measure until every state has an operational statewide PDMP, or until there is an exclusion for those eligible hospitals and CAHs without a statewide PDMP. A few commenters cited the need for additional time for network development and nationwide integration between EHRs and PDMPs. A commenter noted that EHR vendors require a minimum of 24 months to complete development and deployment of any new functionality.

Response: We disagree that requiring the Query of PDMP measure should be delayed until CY 2024. While we appreciate the importance of ongoing work to improve interoperability of PDMP data and integration systems, we also believe that at this time, there is sufficient technical capacity across the country to support finalizing the measure in its current form, requiring a ''yes/no'' attestation. We also understand that there is currently only one state without an operational statewide PDMP, and that this remaining state is moving towards an operational status. Last, we note that we are not finalizing any new technology requirements to support the completion of the actions associated with this measure.

Comment: Many commenters did not support requiring the Query of PDMP measure citing inconsistencies across state lines with regard to interoperability standards, varying degrees of implementation, and the complexities resulting from inconsistent state laws and licensing requirements. Some commenters did not support requiring the Query of PDMP measure due to a lack of standardized privacy and security protocols.

Response: CMS recognizes the work required to improve integration between PDMPs and health care provider health IT systems, as well as the efforts required to standardize data sharing between the systems that may include consideration of privacy and security protocols, and that these efforts are ongoing across the country. While we believe that the importance of querying the PDMP, and the widespread availability of PDMPs at this time is sufficient to finalize requiring the current measure requiring a ''yes/no'' response, we will continue to support efforts to improve the technical approaches supporting data exchange between systems. As these approaches mature, we will work with ONC to consider whether these approaches should be incorporated into the ONC Health IT Certification Program and the Medicare Promoting Interoperability Program.

After consideration of the public comments we received, we are finalizing our proposal to require the Query of PDMP measure beginning with the EHR reporting period in CY 2023. In section IX.H.8. of this final rule, we are finalizing our proposal to remove the associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program, and therefore, we will not be updating 42 CFR 495.24(e)(5) with our finalized changes to the Query of PDMP measure.

(3) Changes to the Query of PDMP Measure To Include Schedule II Opioids and Schedule III and IV Drugs

Under 42 CFR 495.24(e)(5)(iii)(B), the Query of PDMP measure provides that for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. The Query of PDMP measure was adopted in the FY 2019 IPPS/LTCH PPS final rule as one of two measures under the Electronic Prescribing Objective intended to support HHS initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improving coordination of prescribing amongst health care providers, and focusing on the advanced use of CEHRT (83 FR 41648 through 41653).

Under the Controlled Substances Act (CSA),[1092] the Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. A drug's abuse rate is a factor used to determine its classification; for example, Schedule I medications have the highest abuse potential while medications in Schedule V have a low abuse potential. We refer readers to Table IX. H.-02. for information on each Schedule, including abuse potential, medicinal use, if any, and drug examples. For additional information, we refer readers to the listing of drugs and their schedule located at CSA Scheduling at *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*[1093]

[1092] Public Law 91–513, tit. II, 84 Stat. 1236, 1242–84 (1970); codified, as amended, at 21 U.S.C. 801 *et seq.*

[1093] See also *https://www.dea.gov/sites/default/files/2020-04/Drugs%20of%20Abuse%202020-Web%20Version-508%20compliant-4-24-20_0.pdf.*

TABLE IX.H.-02.: CONTROLLED SUBSTANCE SCHEDULES, DESCRIPTIONS, AND EXAMPLES[1094]

Schedule	Description	Examples
Schedule I	No accepted medical use, are unsafe, and hold a high potential for abuse.	Heroin and LSD
Schedule II	Accepted medical use, high potential for abuse, abuse could lead to severe psychological or physical dependence.	Hydrocodone, methadone, Demerol, OxyContin, Percocet, morphine, codeine, and amphetamine
Schedule III	Accepted medical use, less potential for abuse than schedule I or II substances, abuse may lead to moderate or low physical dependence or high psychological dependence.	Tylenol with Codeine and anabolic steroids
Schedule IV	Accepted medical use, low potential for abuse relative to schedule III substances, abuse may lead to limited physical or psychological dependence relative to schedule III substances.	Xanax, Klonopin, Valium, and Ativan
Schedule V	Accepted medical use, low potential for abuse relative to schedule IV substances, abuse may lead to limited physical or psychological dependence relative to schedule IV substances.	Cough syrups containing codeine

PDMPs are operated at the state level and individual state requirements for reporting and use differ from state to state.[1095] Currently, every state collects data on schedules II, III, and IV drugs.[1096] Some states collect information about certain non-controlled substances that are potentially subject to abuse or on all prescription drugs.[1097] While state laws vary, we note that most state PDMPs require physicians and dispensing pharmacists to review a patient's prescribing information for the past twelve months prior to prescribing or dispensing any Schedule II, III, and IV drugs.[1098]

PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. We believe that expanding the requirements of the Query of PDMP measure to include not only Schedule II opioids, and but also Schedule III and IV drugs, this would further support HHS initiatives related to the treatment of opioid and substance use disorders by expanding the types of drugs included in the Query of PDMP measure while aligning with the PDMP requirements in a majority of states. We also believe this expansion to include additional Scheduled drugs would facilitate more informed prescribing practices and improve patient outcomes. Therefore, in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to expand the Query of PDMP measure to include Schedule II opioids, and Schedule III and IV drugs beginning with the EHR reporting period in CY 2023 (87 FR 28579 through 28581).

Proposed Measure Description: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history.

To align with the policy for the Query of PDMP measure with regard to Schedule II opioids, we proposed in the FY 2023 IPPS/LTCH PPS proposed rule that the query of the PDMP for prescription drug history must occur prior to the electronic transmission of an electronic prescription for a Schedule II opioid or Schedule III or IV drug (87 FR 28580). We also proposed that this measure would include all permissible prescriptions and dispensing of Schedule II opioids, and Schedule III or IV drugs, no matter how small the dose prescribed during an encounter. This would allow eligible hospitals and CAHs to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, and controlled substances prescribed in high quantities (87 FR 28580). We also proposed that multiple prescriptions for Schedule II opioids or Schedule III and IV drugs prescribed on the same date, by the same eligible hospital or CAH would not require multiple queries of the PDMP, and at least one query would have to be performed for this measure. We proposed that eligible hospitals and CAHs would have flexibility to query the PDMP using data from CEHRT in

[1094] GAO–21–22, Prescription Drug Monitoring Programs: Views on Usefulness and Challenges of Programs; 21 U.S.C. 812, and the U.S. Drug Enforcement Administration.

[1095] For additional information, we refer readers to *https://www.cdc.gov/drugoverdose/pdf/Leveraging-PDMPs-508.pdf*; *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4605194/*; and *https://www.pdmpassist.org/Policies/Legislative/StatutesAndRegulations*.

[1096] *https://www.pdmpassist.org/State*.

[1097] GAO report, GAO–21–22 Prescription Drug Monitoring Programs.

[1098] *https://www.pdmpassist.org/State*.

any manner allowed under state law (87 FR 28580). We also stated in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28580 through 28581) that should our proposal to remove associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program not be finalized, we proposed to update the regulatory text to reflect these proposed changes at 42 CFR 495.24(e)(5)(iii)(B).

We invited public comment on these proposals. We also invited public comment on whether to expand this measure to include Schedule V or other drugs with the potential for abuse.

Comment: Many commenters expressed support to expand the Query of PDMP measure to include Schedule III and IV drugs. A commenter expressed their belief that understanding a patient's medication history is critical to safe, effective, quality care, particularly when Schedule II opioids and Schedule III and IV drugs are prescribed and dispensed. A commenter expressed its belief that the proposed expansion makes sense because many states also require similar queries.

Response: We thank commenters for their support, and agree that in expanding our measure to also include Schedule III and IV drugs, this will offer eligible hospitals and CAHs a broader clinical picture, aimed at overall patient safety efforts, and agree that expanding these schedules will support better alignment with state regulations.

Comment: A commenter expressed support to include Schedule III and IV drugs, and further recommended that CMS consider similar state laws that require PDMP queries, and how those requirements differ from CMS's requirements.

Response: We thank the commenter for their support. While state laws do vary, we generally understand that many states' PDMPs require physicians and dispensing pharmacists to review each patient's prescribing information for twelve months prior to prescribing or dispensing any Schedule II opioids or Schedule III and IV controlled substances. We may consider the additional feedback in future rulemaking.

Comment: A few commenters did not support expanding the Query of PDMP measure to include Schedule III and IV drugs citing the lack of harmony between state requirements, the potential for confusion, and that some states do not have an operational statewide PDMP.

Response: We disagree with the commenter that expanding the Query of PDMP measure to include Schedule III and IV drugs would contribute to a lack of harmony between state requirements, thereby causing potential confusion. We note that currently, every state collects data on Schedule II opioids, and Schedule III and IV drugs. We believe that in collecting similar data this would minimize the potential for confusion, and instead, promote harmony.

Comment: A few commenters requested clarification on whether the expansion includes all Schedule II drugs.

Response: We proposed expanding the Query of PDMP measure to include Schedule III and IV drugs, but did not propose any changes to the language in the measure description that references Schedule II opioids, and clarify that the Query of PDMP measure does not include or apply to Schedule II drugs that are not opioids (for example, central nervous system stimulants).

Comment: A few commenters recommended furthering the expansion of the Query of PDMP measure to also include Schedule V drugs if there would be value in doing so.

Response: We appreciate the commenters' feedback. While we are not including Schedule V drugs at this time due to the current low potential for abuse in that category, we may consider this in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposals related to the expansion of the Query of PDMP measure to include Schedule II opioids, and Schedule III and IV drugs beginning with the EHR reporting period in CY 2023, as well as the proposed Query of PDMP measure description, and our proposals related to requiring that the query of the PDMP for prescription drug history must occur prior to the electronic transmission of an electronic prescription for a Schedule II opioid or Schedule III or IV drug; that the measure would include all permissible prescriptions and dispensing of Schedule II opioids, and Schedule III or IV drugs, no matter how small the dose prescribed during an encounter; that multiple prescriptions for Schedule II opioids or Schedule III and IV drugs prescribed on the same date, by the same eligible hospital or CAH would not require multiple queries of the PDMP, and at least one query would have to be performed for this measure; and that eligible hospitals and CAHs would have flexibility to query the PDMP using data from CEHRT in any manner allowed under state law . In section IX.H.8. of this final rule, we are finalizing our proposal to remove the associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program, and therefore, we will not be updating 42 CFR 495.24(e)(5) with our finalized changes to the Query of PDMP measure.

(4) Exclusions

In FY 2019 IPPS/LTCH PPS final rule, we finalized exclusions for eligible hospitals and CAHs from reporting the Query of PDMP measure beginning with EHR reporting period in CY 2020 when the measure would have been required by the Medicare Promoting Interoperability Program (83 FR 41653). The finalized exclusions included: (1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and (2) any eligible hospital and CAH that could not report on this measure in accordance with applicable law. We also finalized that beginning with EHR reporting period in CY 2020, an eligible hospital or CAH that qualifies for the e-Prescribing measure exclusion is also excluded from reporting on the Query of PDMP measure (83 FR 41649). We noted our intention to propose a third exclusion where integration with a statewide PDMP was not yet feasible or widely available (83 FR 41652).

In FY 2020 IPPS/LTCH PPS final rule (84 FR 42595), we finalized the removal of the exclusions associated with the Query of PDMP measure, noting that exclusions were not necessary because we finalized the Query of PDMP measure as optional for the EHR reporting period in CY 2020. We also finalized the Query of the PDMP measure as an optional measure for EHR reporting periods in CY 2021 and CY 2022 in FY 2021 IPPS/LTCH PPS final rule (85 FR 58969) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45464), respectively.

In the FY 2023 IPPS/LTCH PPS proposed rule, beginning with the EHR reporting period in CY 2023, we proposed to require the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program (87 FR 28581). We noted that should we finalize our proposal to require the Query of PDMP measure beginning with CY 2023, we believed that exclusions for the measure would be necessary (87 FR 28581). We revisited the exclusions established in the FY 2019 IPPS/LTCH PPS final rule and subsequently removed in the FY 2020 IPPS/LTCH PPS final rule because

the Query of PDMP measure would continue to be an optional measure. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28581), we stated that if we finalize our proposal to require the Query of PDMP measure, we proposed the following exclusions beginning with the EHR reporting period in CY 2023: (1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include drugs from Schedules II, III, and IV, and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and (2) any eligible hospital or CAH that cannot report on this measure in accordance with applicable law. We also referred readers to our proposed policy to redistribute points to the e-Prescribing measure under the Electronic Prescribing Objective should an eligible hospital or CAH claim an exclusion for the Query of PDMP measure for an EHR reporting period (87 FR 28589 through 28592). We also stated in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28581) that should our proposal to remove associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program not be finalized, we proposed to update the regulatory text to reflect these proposed changes at 42 CFR 495.24(e)(5).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41652), we signaled our intention to propose an additional exclusion beginning in CY 2020 for health care providers in states where integration with a statewide PDMP is not yet feasible or not yet widely available. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28581), we expressed our belief that this exclusion is no longer needed given the flexibility of the Query PDMP measure, which requires a ''yes/no'' response, as well as the implementation of PDMPs in all 50 states and several localities and the increasing number of PDMPs offering some degree of integration with EHRs (from 28 PDMPs with at least one type of integration in 2017 to 44 PDMPs that are integrated with HIEs, EHRs, and/or PDSs in 2021 [1099]). We also expressed our belief that broadly requiring this measure across health care providers who may access PDMPs in different ways would help to continue to drive development of improved solutions for PDMP access. In addition, we stated that while we believe the Query of PDMP measure is achievable for eligible hospitals and CAHs and that the proposed exclusions offer significant flexibilities such that most health care providers would be able to meet the measure or claim an exclusion, we welcomed public comment on other barriers, including barriers related to technology solutions, cost, and workflow, that should be considered. We also requested comment on any additional exclusions that we should consider for this measure and may propose in the future.

We invited public comment on these proposals.

Comment: Several commenters expressed support for our proposed exclusions.

Response: We thank commenters for their support.

Comment: Several commenters recommended that CMS consider additional exclusions. Suggestions included allowing an exclusion for eligible hospitals and CAHs in states where EHR–PDMP integration is limited, not possible, or where there is no operational statewide PDMP. A few commenters recommended an exclusion, waiver, or discretion enforcement for the Query of PDMP measure noting it could be burdensome on clinician workflows to compile supporting documentation for attestation using multiple systems, and that this is not the time to put additional burden on clinicians until states have improved their technologies to enable more efficient inquiries. Other commenters recommended that CMS consider exclusions for eligible hospitals and CAHs that are required by the state to use their PDMP outside of, and independent from, their CEHRT, and may not be able to meet the requirements of the Query of PDMP measure.

Response: We thank commenters for their recommendations to include additional exclusions. After reviewing the comments, we agree with commenters that an additional exclusion is needed for eligible hospitals and CAHs for one year. We understand that, for some, accessing state PDMPs can be time-consuming and disruptive to clinical workflow, if technology requires exiting the hospital medical record, connecting with the state PDMP, then compiling supporting documentation for attestation using multiple systems. We also understand that while most states have an operational statewide PDMP, for those eligible hospitals and CAHs located in a state that does not have an operational statewide PDMP, they would need to check a limited county-level PDMP to meet the requirements of the Query of PDMP measure, and we agree, that could interrupt workflows for providers. We believe that this additional, and temporary, exclusion would address concerns raised by CAHs and small rural hospitals where disparities in capacity, and the ability to use IT systems, make meeting the requirements of the Query of PDMP measure costly or burdensome.

We believe that offering an additional exclusion for the CY 2023 EHR reporting period for eligible hospitals or CAHs would provide more time for technologies to improve and for increased EHR–PDMP integration to enable more efficient queries of the PDMP. This exclusion would be available for a limited time (CY 2023), because we believe that one year would offer eligible hospitals and CAHs time to become familiar with new technologies, processes and make necessary adjustments to their workflow with minimal burden and allow for improved readiness.

We appreciate the commenter's recommendation for an exclusion to address when state laws may not allow for an eligible hospital or CAH to meet the requirements of the Query of PDMP measure, and believe the proposed exclusion for ''any eligible hospital or CAH that cannot report on this measure in accordance with applicable law'' would address that scenario.

After consideration of the public comments we received, we are finalizing our proposals with modification to include the following three exclusions for the Query of PDMP measure: (1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include Schedule II, III and IV drugs, and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; (2) Any eligible hospital or CAH that cannot report on this measure in accordance with applicable law; and (3) Any eligible hospital or CAH for which querying a PDMP would impose an excessive workflow or cost burden prior to the start of the EHR reporting period they select in CY 2023. We note that we are finalizing this third exclusion related to workflow and cost burden on a time-limited basis for those eligible hospitals and CAHs that believe they would face significant burden associated with querying a PDMP at least once when reporting the measure during an EHR

[1099] PDMP Policies and Capabilities: Results From 2021 State Assessment, September 2021, *https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202021%20Assessment%20Results_20210921.pdf.*

reporting period in CY 2023. This exclusion will no longer be available for EHR reporting periods after CY 2023. We expect that those eligible hospitals and CAHs claiming this exclusion in 2023 will be able to utilize the additional time provided by this time-limited exclusion to resolve any remaining barriers to reporting the measure. In section IX.H.8. of this final rule, we are finalizing our proposal to remove the associated regulatory text related to measures and objectives for the Medicare Promoting Interoperability Program, and therefore, we will not be updating 42 CFR 495.24(e)(5) with our finalized changes to the Query of PDMP measure.

d. Future Direction

While we believe that finalizing our proposals for the Query of PDMP measure are feasible and appropriate at this time, we continue to work with industry and Federal partners to advance common standards for the exchange of information between PDMPs, EHRs, pharmacy information systems, and exchange networks. We believe this work will ultimately allow us to achieve our ideal state, where we would further modify the Query of PDMP measure to be numerator/denominator-based, and require use of standardized functionality within CEHRT to support the actions associated with the measure while reporting on a numerator and denominator. We will continue to collaborate with ONC to monitor developments across the industry, efforts made toward advancing relevant standards, and plan to revisit this measure in the future to explore further specifying health IT requirements if they become available and are incorporated into the ONC Health IT Certification Program.

Federally supported activities continue to focus on developing and refining standards-based approaches to enable effective integration into clinical workflows; exploring emerging technical solutions to enhance access to and use of PDMP data; and providing technical resources to a variety of interested parties to advance and scale the interoperability of health IT systems and PDMPs. Moreover, updates to certified health IT systems incorporating application programming interfaces (APIs) based on HL7® FHIR® standard version Release 4 (85 FR 25642) can help support future technical approaches that enable more seamless exchange of data between CEHRT and PDMP systems. For more information about current and emerging standards related to PDMP data capture and exchange, we refer readers to the ONC Interoperability Standards Advisory.[1100]

e. Technical Update to the E-Prescribing Measure

The ONC 21st Century Cures Act final rule (85 FR 25642; 85 FR 25660 through 25661) retired the ''drug-formulary and preferred drug list checks'' certification criterion at 45 CFR 170.315(a)(10) which was associated with measures under the Electronic Prescribing Objective for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (80 FR 62882 and 83 FR 59817). ONC retired this criterion after January 1, 2022 (85 FR 26661).

In the CY 2021 PFS final rule, we finalized that the ''drug-formulary and preferred drug list checks'' criterion will no longer be associated with measures under the Electronic Prescribing Objective and will no longer be required to meet the CEHRT definition for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, beginning with CY 2021 EHR reporting and performance periods (85 FR 84815 through 84825).

In the FY 2022 IPPS/LTCH PPS final rule, we inadvertently omitted a revision to TABLE IX.F.-02.: Objectives and Measures for the Medicare Promoting Interoperability Program in 2022 to reflect this change and included the text ''queried for a drug formulary'' in the measure description and in the numerator of the e-Prescribing measure (86 FR 45484). In an effort to more clearly capture the previously established policy finalized in the CY 2021 PFS final rule with respect to the e-Prescribing measure, we proposed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28582) to revise the measure description in TABLE 56 to read, ''For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are transmitted electronically using CEHRT'' and the numerator will be updated to read to indicate ''[t]he number of prescriptions in the denominator generated and transmitted electronically'' to reflect the removal of the health IT certification criterion ''drug-formulary and preferred drug list checks'' (86 FR 65478).

We invited comment on our proposal.

Comment: A few commenters supported our proposal.

Response: We thank commenters for their support. After consideration of the public comments we have received, we are finalizing our proposal to revise the measure description in [TABLE XX] to read ''For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are transmitted electronically using CEHRT,'' and the numerator will be updated to read to indicate ''[t]he number of prescriptions in the denominator generated and transmitted electronically'' to reflect the removal of the health IT certification criterion ''drug-formulary and preferred drug list checks''.

4. Health Information Exchange (HIE) Objective: Addition of An Alternative Measure for Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

a. Background on the Health Information Exchange Objective

The Health Information Exchange (HIE) Objective and its associated measures for eligible hospitals and CAHs hold particular importance because of the role they play within the care continuum. In addition, these measures encourage and leverage interoperability on a broader scale and promote health IT-based care coordination. The Health Information Exchange Objective currently includes three measures: Support Electronic Referral Loops by Sending Health Information, Support Electronic Referral Loops by Receiving and Reconciling Health Information, and Health Information Exchange Bi-Directional Exchange. For background on this objective and its associated measures, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41656 through 41661), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42596 through 42597), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58969), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45465 through 45470).

In the FY 2022 IPPS/LTCH PPS final rule, we finalized the HIE Bi-Directional Exchange measure, under the Health Information Exchange Objective (86 FR 45465 through 45470). The HIE Bi-Directional Exchange measure is worth 40 points, the maximum number of points of the Health Information Exchange Objective, and was finalized as an alternative to reporting on the two existing Health Information Exchange Objective measures: The Support Electronic Referral Loops by Sending Health Information measure (42 CFR 495.24(e)(6)(ii)(A)) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (42 CFR 495.24(e)(6)(ii)(B)). To

[1100] *https://www.healthit.gov/isa/allows-a-provider-request-a-patients-medication-history-a-state-prescription-drug-monitoring.*

meet the measure requirements, eligible hospitals and CAHs must attest to the following statements:

- *Statement 1:* Participating in an HIE to enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.
- *Statement 2:* Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.
- *Statement 3:* Using the functions of CEHRT to support bi-directional exchange with an HIE.

We stated that, by enabling bi-directional exchange of information between health care providers and aggregating data across health care providers with disparate systems, HIEs (including a wide range of organizations facilitating health information exchange) can bring together the information needed to create a true longitudinal care record and support improved care coordination by facilitating timely access to robust health information across care settings (86 FR 45465). We further described how participation in HIEs can amplify health care providers' capacity to share information beyond what a health care provider can achieve through the sending and receiving actions described in the existing measures under the Health Information Exchange Objective, for instance, by facilitating information exchange when a health care provider is unaware of another health care provider's need to receive information about a patient (86 FR 45466). By finalizing this measure for eligible hospitals and CAHs, we sought to ensure that eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program would be rewarded for connecting to exchange arrangements that can enable this type of robust information sharing.

b. Background on TEFCA

Section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, amended section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj–11(c)), and required HHS to take steps to advance interoperability for the purpose of ensuring full network-to-network exchange of health information. Specifically, Congress directed the National Coordinator to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' Since the enactment of the 21st Century Cures Act, HHS has pursued development of a Trusted Exchange Framework and Common Agreement, or TEFCA. ONC's goals for TEFCA are: [1101]

Goal 1: Establish a universal policy and technical floor for nationwide interoperability.

Goal 2: Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.

Goal 3: Enable individuals to gather their health care information.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20537), we requested comment on whether eligible hospital or CAH participation in TEFCA should be considered a health IT activity that could count for credit within the Health Information Exchange Objective in lieu of reporting on measures for this objective. We received comments in support of this concept, although some commenters disagreed indicating that they were concerned about adding additional burden (83 FR 41669).

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25631 through 25634), in which we proposed the HIE Bi-Directional Exchange measure for eligible hospitals and CAHs, we noted that the proposed attestation statements for the measure did not explicitly refer to participation in a health information network or partnering with a health information network that enables exchange under TEFCA. However, we stated TEFCA was likely to be an important way for eligible hospitals and CAHs to enable bi-directional health information exchange in the future and that we would continue to explore ways to provide further guidance or update this measure to align with the use of health information networks that enable exchange under TEFCA in the future (86 FR 25634). In the final rule, we noted that several commenters were encouraged to see our acknowledgement that this measure could align with the efforts on TEFCA (86 FR 45468).

Since the publication of the FY 2022 IPPS/LTCH PPS final rule, important additional developments have occurred with respect to TEFCA.[1102] On January 18, 2022, ONC announced a significant TEFCA milestone by releasing the Trusted Exchange Framework [1103] and Common Agreement Version 1.[1104] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement for Nationwide Health Information Interoperability Version 1 (also referred to as Common Agreement) is a contract that advances those principles. The Common Agreement and the incorporated by reference Qualified Health Information Network (QHIN) Technical Framework Version 1 (QTF) [1105] establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other—all under commonly agreed-to terms. The Common Agreement is a legal contract that QHINs [1106] sign with the ONC Recognized Coordinating Entity (RCE),[1107] a private-sector entity that implements the Common Agreement and ensures QHINs comply with its terms.

The technical and policy architecture of how exchange occurs under TEFCA follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at different levels, such as health information networks, care practices, hospitals, public health agencies, and Individual

[1101] See *https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch*.

[1102] For more information on current developments related to TEFCA, we refer readers to *www.HealthIT.gov/TEFCA*.

[1103] Trusted Exchange Framework (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf*.

[1104] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

[1105] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf*.

[1106] The Common Agreement defines a QHIN as ''to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

[1107] In August 2019, ONC awarded a cooperative agreement to The Sequoia Project to serve as the initial RCE. The RCE will operationalize and enforce the Common Agreement, oversee QHIN-facilitated network operations, and ensure compliance by participating QHINs. The RCE will also engage interested parties to create a roadmap for expanding interoperability over time. *https://sequoiaproject.org/onc-awards-the-sequoia-project-a-cooperative-agreement-for-the-trusted-exchange-framework-and-common-agreement-to-support-advancing-nationwide-interoperability-of-electronic-health-information/*.

Access Services (IAS) [1108] Providers.[1109] QHINs connect directly to each other to facilitate nationwide interoperability, and each QHIN can connect Participants, which can connect Subparticipants.[1110] Compared to most nationwide exchange today, the Common Agreement includes an expanded set of Exchange Purposes beyond Treatment to include Individual Access Services, Payment, Health Care Operations, Public Health, and Government Benefits Determination [1111]—all built upon common technical and policy requirements to meet key needs of the U.S. health care system.[1112] This flexible structure allows interested parties to participate in the way that makes the most sense for them, while supporting simplified, seamless exchange.

The QTF,[1113] which was developed and released by the RCE, describes the functional and technical requirements that a Health Information Network (HIN) [1114] must fulfill to serve as a QHIN under the Common Agreement. The QTF specifies the technical underpinnings for QHIN-to-QHIN exchange and certain other responsibilities described in the Common Agreement. The technical and functional requirements described in the QTF enable information exchange modalities, including querying and message delivery across participating entities.

In general, the information to be exchanged within the TEFCA ecosystem allows for the use of the Health Level Seven (HL7®) Implementation Guide for Clinical Document Architecture (CDA®) Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1 (C–CDA 2.1) document format, including data defined as part of U.S. Core Data for Interoperability (USCDI), with allowance for flexibility to further expand the content to support a multitude of use cases.[1115] The Common Agreement and the QTF do not require HL7® Fast Healthcare Interoperability Resource (FHIR®)-based exchange. TEFCA allows for the optional exchange of FHIR content using more traditional, established standards to enable the transport of that content. However, TEFCA can nonetheless be a strong catalyst for network enablement of FHIR maturation. To that end, the RCE released a three-year FHIR Roadmap for TEFCA Exchange, which lays out a deliberate strategy to add FHIR-based exchange under TEFCA in the near future.[1116]

c. New Enabling Exchange Under TEFCA Measure

In 2022, prospective QHINs are anticipated to begin signing the Common Agreement and applying for designation. The RCE will then begin onboarding and designating QHINs to share information. In 2023, HHS expects interested parties across the care continuum to have increasing opportunities to enable exchange under TEFCA. Specifically, this would mean such interested parties would be: (1) signatories to either the Common Agreement or an agreement that meets the flow-down requirements of the Common Agreement (called a Framework Agreement [1117] under the Common Agreement), (2) in good standing (that is not suspended) under that agreement, and (3) enabling secure, bi-directional exchange of information to occur, in production. TEFCA is expected to give individuals and entities easier, more efficient access to more health information. The Common Agreement will require strong privacy and security protections for all entities who elect to participate, including entities not covered by the Health Insurance Portability and Accountability Act (HIPAA).[1118]

By connecting to an entity that connects to a QHIN or connecting directly to a QHIN, an eligible hospital or CAH can share health information in the same manner as described in the attestation statements previously finalized for the HIE Bi-Directional Exchange measure (42 CFR 495.24(e)(6)(ii)(C)). By connecting to an entity that connects to a QHIN, or connecting directly to a QHIN, that supports sharing information on patients as part of a Framework Agreement,[1119] an eligible hospital or

[1108] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1109] The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1110] For the Common Agreement definitions of QHIN, Participant, and Subparticipant, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 8–12 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1111] For the Common Agreement definitions of Payment, Health Care Operations, Public Health, and Government Benefits Determination, *see* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6–10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1112] Exchange Purpose(s): means the reason, as authorized by [the] Common Agreement including the Exchange Purposes SOP, for a Request, Use, Disclosure, or Response transmitted via QHIN-to-QHIN exchange as one step in the transmission. Authorized Exchange Purposes are: Treatment, Payment, Health Care Operations, Public Health, Government Benefits Determination, Individual Access Services, and any other purpose authorized as an Exchange Purpose by the Exchange Purposes SOP, each to the extent permitted under Applicable Law, under all applicable provisions of [the] Common Agreement, and, if applicable, under the implementation SOP for the applicable Exchange Purpose. Definitions for each of these exchange purposes can be found in the Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 *(Jan. 2022), https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1113] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[1114] ''Health Information Network'' under TEFCA has the meaning assigned to the term ''Health Information Network or Health Information Exchange'' in the information blocking regulations at 45 CFR 171.102.

[1115] User's Guide to the Trusted Exchange Framework and Common Agreement—TEFCA (Jan 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/Common-Agreement-Users-Guide.pdf.*

[1116] FHIR® Roadmap for TEFCA Exchange Version 1 (Jan. 2022), *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/FHIR-Roadmap-v1.0_updated.pdf.*

[1117] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' See Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1118] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1119] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan.

Continued

CAH would be thereby enabling bi-directional exchange with other health care providers as described in Statement 1 of the HIE Bi-Directional Exchange measure. Since participation in a Framework Agreement as a QHIN, Participant, or Sub-participant will be open to all qualifying entities and will not be restricted by use of a single vendor, a connection via a Framework Agreement would also satisfy the requirements of Statement 2 of the HIE Bi-Directional Exchange measure. Finally, as discussed previously, the technical requirements for exchanging information by entities through the Common Agreement and Framework Agreements utilize standards included in certified technology referenced under the CEHRT definition (see 42 CFR 495.4), including the ability to exchange and receive data using the C–CDA standard (see certification criteria at 45 CFR 170.315(b)(1) and (2)), thus health care providers participating in a Framework Agreement can use the functions of CEHRT to support bi-directional exchange with an HIE.

To offer health care providers more opportunities to earn credit for the Health Information Exchange Objective, and given the alignment between enabling exchange under TEFCA and the existing HIE Bi-Directional Exchange measure, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28582 through 28585), we proposed to add an additional measure through which an eligible hospital or CAH could earn credit for the Health Information Exchange Objective by connecting to an entity that connects to a QHIN or connecting directly to a QHIN. Specifically, we proposed to add the following new measure to the Health Information Exchange Objective beginning with the EHR reporting period in CY 2023: Enabling Exchange Under TEFCA measure. We proposed that eligible hospitals and CAHs would have three reporting options for the Health Information Exchange Objective: (1) report on both the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, (2) report on the HIE Bi-Directional Exchange measure, or (3) report on the proposed Enabling Exchange Under TEFCA measure.

We proposed that the Enabling Exchange Under TEFCA measure would be worth the total amount of points available for the Health Information Exchange Objective. Under the current scoring methodology finalized in the FY 2022 IPPS/LTCH PPS final rule, the Health Information Exchange Objective is worth a total of 40 points (86 FR 45466). We noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28589) that we were proposing changes to the scoring methodology beginning with the EHR reporting period in CY 2023 such that the Health Information Exchange Objective would be worth no more than 30 points. Therefore, under our proposal, the proposed Enabling Exchange Under TEFCA measure would be worth 30 points. We proposed this change to the scoring methodology as a result of our proposal in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28579) to make the Query of PDMP measure required and worth 10 points. However, we stated that should we not finalize the Query of PDMP measure proposal, we proposed that the Enabling Exchange Under TEFCA measure would be worth 40 points (the current total point value of the Health Information Exchange Objective). In no case could more than 40 points total be earned for the Health Information Exchange Objective. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28593 through 28594), we proposed to remove text for the objectives and measures from paragraph (e) under 42 CFR 495.24 beginning in CY 2023. We stated that if we do not finalize that proposal, we would revise 42 CFR 495.24(e) to reflect the addition of the proposed Enabling Exchange Under TEFCA measure.

We stated that we believe the new measure for enabling exchange under TEFCA that we proposed would incentivize eligible hospitals and CAHs to exchange information by connecting directly or indirectly to a QHIN and support health information exchange at a national level. We believe that fulfillment of this measure is an extremely high value action. The overall TEFCA goal of establishing a universal floor of interoperability across the country aligns with our commitment to promoting and prioritizing interoperability and exchange of healthcare data. Incentivizing providers to enable exchange under TEFCA is a critical component to advancing healthcare data exchange nationwide. We proposed that eligible hospitals and CAHs would report the Enabling Exchange Under TEFCA measure by attestation, and the measure would require a ''yes/no'' response. A ''yes'' response would enable eligible hospitals and CAHs to earn the proposed 30 points allotted to the Health Information Exchange Objective. Further, we proposed that this measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data were entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

We proposed that eligible hospitals and CAHs would attest to the following:

- Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) (in good standing, that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.
- Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.

Similar to the HIE Bi-Directional Exchange measure, to successfully attest to this measure, we proposed the eligible hospital or CAH must use the capabilities of CEHRT to support bi-directional exchange under a Framework Agreement, which includes capabilities that support exchanging the clinical data within the Common Clinical Data Set (CCDS) or the United States Core Data for Interoperability (USCDI). This is consistent with the other measures under the Health Information Exchange Objective, which point to the use of CEHRT to support the exchange of the clinical data within the CCDS or the USCDI. We note that, beginning in 2023, when this measure would be available for eligible hospitals and CAHs to report eligible hospitals and CAHs must use certified health IT that has been updated consistent with the 2015 Edition Cures Update, including updates to relevant certification criteria to reference the USCDI instead of the CCDS (85 FR 25642).

We stated that we believe there are numerous certified health IT capabilities that can support bi-directional exchange under a Framework Agreement. For instance, participants may exchange information under a Framework Agreement by using technology certified to the criterion at 45 CFR 170.315(b)(1), ''Care

2022) *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

coordination—Transitions of care,'' to transmit C–CDAs across a network. Where supported, participants could also utilize API technology certified to either the criterion at 45 CFR 170.315(g)(8), ''Design and performance—Application access—data category request,'' or (g)(10), ''Design and performance—Standardized API for patient and population services,'' as finalized in the ONC 21st Century Cures Act final rule (85 FR 25742), to enable exchange of data in the USCDI from a participant's EHR. Additional certified health IT modules may also support exchange of information under a Framework Agreement for transitions of care, including modules certified to certification criteria at 45 CFR 170.315(g)(7), ''Design and performance—Application access—patient selection,'' and (g)(9), ''Design and performance—Application access—all data request,'' which support information exchange via API; the certification criterion at 45 CFR 170.315(e)(1), ''Patient engagement—View, download, and transmit to 3rd party,'' which supports patient access to their information; and the certification criterion at 45 CFR 170.315(g)(6), ''Design and performance—Consolidated CDA creation performance,'' which supports creation of a summary of care record. We recognize that entities that will connect directly or indirectly to a QHIN are currently interacting with health care providers using certified health IT in a variety of ways, and, as with the HIE Bi-Directional Exchange measure, believe that we should allow for substantial flexibility in how health care providers use certified health IT to exchange data under a Framework Agreement.

We stated that the Enabling Exchange Under TEFCA measure could offer health care providers an alternative to earn credit for the Health Information Exchange Objective. The Enabling Exchange Under TEFCA measure would not require an eligible hospital or CAH to assess whether they participate in a health information exchange that meets the attributes of attestation Statement 2 under the HIE Bi-Directional Exchange measure regarding exchange across a broad network of unaffiliated exchange partners including those using disparate EHRs. These attributes are key to the goals of TEFCA, which aims to offer health care providers a uniform set of expectations around information sharing regardless of which network for information exchange they participate in.

We invited public comment on these proposals.

Comment: Many commenters expressed support for the proposal. A few commenters believed the measure would allow health care providers to have options to meet this objective that enable more broad-based data exchange across the health ecosystem and utilize TEFCA when appropriate. Many commenters expressed support for the adoption of the Enabling Exchange Under TEFCA measure as a means to advance health information exchange and interoperability on a national level. A commenter suggested that this improved means toward interoperability would help optimize patient care. Another commenter believed the measure would support compliance with the regulations finalized in the ONC 21st Cures Act Final Rule. Several commenters noted the measure would promote capabilities for bi-directional exchange, which they believed would be critical to advancing effective interoperability. A few commenters noted the measure would help improve health care provider reporting. A few commenters thanked CMS for a flexible model that would allow newly created programs to mature and reduce burdens associated with participation requirements, all while incentivizing participation in TEFCA.

Response: We thank commenters for their support and feedback. We agree that adding a third measure under the Health Information Exchange Objective to offer an additional path to earn credit and accelerate the bi-directional exchange of health information is consistent with the goals of the HIE Objective and aligns with the overall goal to promote nationwide interoperability.

Comment: A few commenters expressed specific support for CMS' and ONC's collaboration in making TEFCA a key pillar in the nationwide strategy to establish a ''floor'' and framework for health data interoperability and exchange.

Response: We thank commenters for recognizing our continued efforts toward alignment and inter-agency collaboration. CMS and ONC will continue to collaborate and work with interested parties on TEFCA implementation to support advancements in health information exchange.

Comment: A few commenters expressed support for the Enabling Exchange under TEFCA measure as a means to position TEFCA to be a more effective mechanism for data delivery for a range of important use cases, such as patient access and patient-centered care.

Response: We thank commenters for their support. We believe that widespread adoption of the Common Agreement will facilitate patients, health care providers, payers, HINs, health IT developers, and other interested parties having access to data when and where it is needed to better support patient care.

Comment: Many commenters expressed support around the optional or alternative nature of this measure, specifically citing concerns around the technical maturity and functionality of TEFCA. Several commenters cautioned against requiring this measure without first confirming that the infrastructure is mature and widespread enough to support the requirements. For example, a few commenters expressed concern around whether there would be an available QHIN in which to participate in time for the 2023 reporting period.

Response: We thank the commenters for their support and acknowledge these concerns. We note that TEFCA will be operationalized in 2022 before the start of the EHR reporting period in CY 2023, and that the Enabling Exchange under TEFCA measure was proposed as an optional alternative for the HIE Objective beginning with the EHR reporting period in CY 2023. We anticipate that TEFCA will provide a valuable pathway for health care providers to access information needed to support value-based care, care management, and population health. By connecting a set of nationwide, trusted health information networks and creating baseline legal and technical requirements that would enable secure information sharing across different networks nationwide, TEFCA has the potential to significantly reduce the need for duplicative network connectivity interfaces, which are costly, complex to create and maintain, and an inefficient use of health care provider and health IT developer resources. As more eligible hospitals and CAHs enable exchange under TEFCA and are able to report on this new measure, we believe technical maturity and functionality of health information exchange will also continue to significantly improve.

Comment: A commenter suggested CMS should consider the impact on eligible hospitals and CAHs if TEFCA participation were to become unstable due to entities that facilitate exchange not meeting relevant terms and conditions and offer a hardship exception if a health care provider's ability to exchange information under TEFCA were to be limited or terminated due to suspension/termination of an entity which a provider relies upon in

order to exchange information under TEFCA. Another commenter expressed related concerns and stated that CMS should add exceptions to the Enabling Exchange under TEFCA measure to allow for potential trickle-down effect disruptions that are beyond the control of eligible hospitals and CAHs.

Response: We understand that there could be a scenario in which an eligible hospital or CAH is unable to exchange information under the Common Agreement or a Framework Agreement for the duration of a reporting period using a specific entity due to that entity being terminated or suspended under the terms of the Common Agreement or an associated Framework Agreement. In such cases, an eligible hospital or CAH could explore connecting to a different QHIN, Participant, or Subparticipant, which could enable the exchange of health information by the eligible hospital or CAH, limit the disruption, and potentially allow the eligible hospital or CAH to continue to attest to the statements required for the measure. If the eligible hospital or CAH is not able to connect to a different QHIN, Participant, or Subparticipant, the eligible hospital or CAH would likely no longer be able to attest ''yes'' to the statements required for the measure. In such cases, the eligible hospital or CAH could select one or more of the other measures that are included under the HIE Objective (for instance, the HIE Bi-directional measure could still be relevant if an eligible hospital or CAH can continue to use a network previously connected under TEFCA). We do not believe a hardship exception would be necessary for the Enabling Exchange Under TEFCA measure because it is an optional measure.

Comment: Several commenters, in addition to expressing support for the proposed measure, offered additional recommendations for future efforts. A few commenters suggested continued collaboration among CMS, ONC and other entities to support TEFCA implementation. A commenter recommended CMS consider future measures that would further support health care provider interactions with payers for processes such as coverage requirements discovery and submission of prior authorization requests. Another commenter noted there are similar, already existing private sector solutions that seek to accomplish the same goals as this measure. This commenter recommended government participation in those efforts to expand impact of this measure. A commenter recommended CMS consider innovative technologies like blockchain within TEFCA.

Response: We appreciate these recommendations. ONC and CMS will continue to work together to explore how TEFCA can support a wide range of CMS programs and activities. Furthermore, we note that ONC and CMS invite collaboration around TEFCA by all private sector solutions that are seeking to accomplish the same goal of advancing interoperability nationwide.

Comment: Several commenters did not support the proposed measure. These commenters suggested CMS proceed with caution when adding a new measure related to TEFCA before additional TEFCA milestones are achieved, citing uncertainties around how TEFCA will function and the lack of details around participation to fully understand all of its implications. A commenter suggested CMS wait to implement the measure until TEFCA transitions from the ''TEFCA Transitional Council'' advisory group to the full ''TEFCA Governing Council,'' which, according to the commenter, would signal that the QHINs are operational and ready to govern the Common Agreement themselves. Another commenter cited the lack of standard operating procedures released by the RCE. This commenter believed that the measure could encourage eligible hospitals and CAHs to shift from more mature and interoperable networks, leading to an overall decrease in interoperability. Another commenter suggested CMS postpone this measure until at least CY 2024, after data exchange under TEFCA has been initiated.

Response: We thank the commenters for their feedback and acknowledge these concerns. The Trusted Exchange Framework and the Common Agreement Version 1 were published in January 2022, and entities will soon be able to apply to be designated as QHINs. By proposing this as an optional measure, hospitals may opt into reporting if they are ready to exchange information under TEFCA, but including this optional measure does not create any requirement for eligible hospitals and CAHs to exchange information under TEFCA if they choose not to at this time due to concerns such as those expressed by commenters around postponing the measure. We are hopeful that the finalization of this proposal will help incentivize readiness as well as increase participation in exchange under TEFCA. We disagree with commenters that this measure should be postponed, or that the measure would pose a threat to current progress towards interoperability.

Comment: A few commenters did not support the measure because they believed it duplicates the HIE Bi-Directional Exchange measure and therefore may be confusing to health care providers. These commenters state that the current HIE Bi-Directional measure would allow participants in TEFCA to claim credit for the objective. A commenter recommended a step-wise approach for facilities to allow a ramp up to compliance while meeting other interoperability requirements simultaneously.

Response: We thank the commenters for their feedback and acknowledge this concern. We disagree that the Enabling Exchange under TEFCA measure is duplicative of the HIE Bi-Directional Exchange measure. Instead, we believe the optional Enabling Exchange under TEFCA measure would complement the HIE Bi-Directional Exchange measure by providing a convenient option for those who enable exchange under TEFCA to claim credit for the HIE objective. At this time, we believe, it is unclear what a step-wise approach would look like, given the binary nature of TEFCA participation, and do not believe a step-wise approach would more effectively support participation. We expect that many eligible hospitals and CAHs will already be participating in health information networks that will enable exchange under the TEFCA and would not need to engage in an incremental process in order to begin attesting to this measure in 2023.

Comment: Several commenters offered recommendations for CMS with regard to this measure. A few commenters suggested CMS should add this optional measure for eligible clinicians to report under the Promoting Interoperability performance category of MIPS. Several commenters suggested CMS provide resources on the benefits of TEFCA and reasons why eligible hospitals and CAHs should invest in exchanging information under TEFCA, including how eligible hospitals or CAHs can justify additional investments to hospital boards and communities for exchange under TEFCA.

Response: We appreciate this feedback and will take these comments into consideration for future rulemaking. Regarding a complementary proposal for eligible clinicians in MIPS, we refer readers to the 2023 PFS NPRM, in which we have proposed a similar measure for inclusion in the Promoting Interoperability performance category.[1120]

[1120] See *https://www.federalregister.gov/public-inspection/2022-14562/medicare-and-medicaid-programs-calendar-year-2023-payment-policies-under-the-physician-fee-schedule.*

Regarding resources on the benefits of TEFCA and reasons why eligible hospitals and CAHs should invest in exchanging information under TEFCA, we note that some resources are already available on this topic, including an information resource developed by the RCE entitled ''The Nationwide Network Based on the Common Agreement Benefits for Health Care Providers Across the Continuum.'' [1121] However, we will continue to collaborate with ONC and other partners to identify resources that can help providers to better understand the benefits of TEFCA, and invite public comment on what kinds of resources would be most useful to stakeholders.

Comment: Commenters recommended that the alternative measure require eligible hospitals and CAHs to attest to facilitating exchange for all required Exchange Purposes, including Individual Access Services. A commenter recommended that CMS should increase incentives for the use of HIEs for Exchange Purposes beyond Treatment, so as not to go against information blocking rules, furthering the need for HIEs to facilitate data exchange for a broad range of purposes authorized by law. Another commenter suggested that CMS and ONC coordinate to ensure measures that reference TEFCA include measurement of participation in the Individual Access Services Exchange Purpose in addition to Treatment, Payment, and Health Care Operations Exchange Purposes.

Response: For this Enabling Exchange under TEFCA measure, we have focused on aligning with the goals of the HIE Objective which pertains to care coordination and exchange between health care providers. However, we will consider whether this model can be applied to other Promoting Interoperability objectives that may align with other TEFCA Exchange Purposes, such as IAS, in the future. We do believe that HIEs can support other Exchange Purposes beyond Treatment and will continue to explore ways to incentivize these use cases. Finally, we do not believe there is any conflict between incentives for care coordination under this proposal and the information blocking rules. We refer readers to the resources around TEFCA cited in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28582 through 28585).[1122] [1123] [1124] [1125] [1126] [1127] CMS will continue to explore additional opportunities to provide further education and outreach regarding TEFCA.

Comment: A commenter requested clarification from CMS on requirements for health care providers participating in multiple state HIEs, including hospitals near state borders.

Response: For health care providers near state borders, there is no specific requirement that an eligible hospital or CAH must ensure that exchange enabled under TEFCA includes health care providers in a neighboring state with which a health care provider may need to share information. However, we believe that by enabling exchange across networks nationwide, providers exchanging information under TEFCA will be more likely to be able to effectively exchange information across state lines.

Comment: A commenter suggested CMS should clarify that the exchange of patient summaries or other patient data need not occur for all unique patients but only as needed or requested. A commenter requested clarity on the definition of ''enable'' in the context of this measure.

Response: We thank commenters for their feedback. The first attestation statement, as proposed, would require an eligible hospital or CAH to enable secure, bi-directional exchange of information to occur under a Framework Agreement. As we noted in our discussion of the final policy for the HIE Bi-Directional Measure (86 FR 45468), enabling bi-directional exchange does not mean that an eligible hospital or CAH would be required to conduct information transactions that are not clinically necessary. Rather, it means that an eligible hospital or CAH has established the capabilities necessary to complete exchanges of information for its patients at the appropriate time. In the case of the Enabling Exchange under TEFCA measure, this means the capabilities to exchange information under a Framework Agreement.

Comment: Commenters requested clarity around what data is to be exchanged and whether there is an expectation to incorporate any of the exchanged information into the patient chart as with the current HIE Objective measure ''Support Electronic Referral Loops by Receiving and Reconciling Health Information,'' for instance, through reconciliation of parsed data from received C–CDAs.

Response: We note that, at a minimum, TEFCA requires the exchange of all available data elements from USCDI Version 1.[1128] Health care providers participating in a Framework Agreement and attesting to this measure would be required to exchange data according to the terms of the Framework Agreement. Regarding reconciliation of information, the requirements for the measure are limited to attesting to the statements related to engaging in bi-directional exchange under a Framework Agreement using the functions of CEHRT. There are no additional explicit requirements related to how the health care provider must incorporate information received under the Framework Agreement into the patient's record.

Comment: Another commenter requested clarity on the definition of ''calculated'' in the context of this measure.

Response: Thank you for the comment. We wish to clarify that the proposed attestation statements do not require an eligible hospital or CAH to perform calculations, as part of this measure, such as those necessary for measures that are based on reporting of a numerator and denominator and count unique patients or actions. Therefore, we are not finalizing our proposal that this measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT, as this proposal is not relevant to the measure.

Comment: A commenter requested CMS provide further clarity on how to document completion of this measure and what would suffice as a

[1121] See *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/RCE_Leveraging-Nationwide-Exchange_Providers_1.2-RCE-Final.pdf.*

[1122] Blog post, 3...2...1...TEFCA is Go for Launch. Published: January 19, 2022. *https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch.*

[1123] Website, Trusted Exchange Framework and Common Agreement (TEFCA), January 2022. *https://www.HealthIT.gov/TEFCA.*

[1124] Policy document, The Trusted Exchange Framework (TEF): Principles for Trusted Exchange, January 2022. Available at *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[1125] Policy document, Common Agreement for Nationwide Health Information Interoperability Version 1, January 2022. Available at *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[1126] Policy document, Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0, January 2022. Available at *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[1127] Press release, ONC Awards The Sequoia Project a Cooperative Agreement for the Trusted Exchange Framework and Common Agreement to Support Advancing Nationwide Interoperability of Electronic Health Information. Published September 4, 2019. Available at *https://sequoiaproject.org/onc-awards-the-sequoia-project-a-cooperative-agreement-for-the-trusted-exchange-framework-and-common-agreement-to-support-advancing-nationwide-interoperability-of-electronic-health-information/.*

[1128] See QHIN Technical Framework, at QTF–047 and QTF–092, available at *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

demonstration of the capacity to exchange information with others efficiently and effectively.

Response: In order to successfully ''complete'' this measure, eligible hospitals and CAHs must attest to the required statements. Completion of the measure would be limited to attesting to the required statements. For audit purposes, eligible hospitals and CAHs should retain evidence of their agreement with a QHIN, Participant, or Subparticipant that includes the terms of a Framework Agreement.

Comment: A few commenters who supported the measure also expressed some concerns regarding this measure. A commenter believed CMS is adding technical requirements without confirming that the functionality of vendor systems is useful with regard to system integration, user interface, or workflow of the technology, placing this burden on eligible hospitals and CAHs. This commenter requested that CMS and ONC reassess measurement of compliance for vendor systems. Another commenter cautioned CMS against offering a measure based on enabling information exchange under TEFCA because they believed TEFCA implementation will be slow and additional milestones should be confirmed and achieved first.

Response: We appreciate commenters' feedback and acknowledge these concerns. In order to attest to this measure, the eligible hospital or CAH must use the functions of CEHRT to connect directly or indirectly to a QHIN. As noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28585) and reiterated above, there are currently a number of certified health IT capabilities that support the technical requirements for exchange under TEFCA, thus these capabilities would be useful for participation in exchange under TEFCA and earning credit under this measure. We believe that by finalizing this measure as optional, eligible hospitals and CAHs can opt in to reporting it once they are ready to enable exchange under TEFCA and are confident in the infrastructure.

After consideration of the public comments we received, we are finalizing our proposal to add an additional measure through which an eligible hospital or CAH could earn credit for the Health Information Exchange Objective by connecting to an entity that connects to a QHIN or connecting directly to a QHIN. We are finalizing our proposal to add this measure to the Health Information Exchange Objective beginning with the EHR reporting period in CY 2023: Enabling Exchange Under TEFCA measure. We are finalizing our proposal that eligible hospitals and CAHs will now have three reporting options for the Health Information Exchange Objective: (1) Report on both the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, (2) report on the HIE Bi-Directional Exchange measure, or (3) report on the Enabling Exchange Under TEFCA measure. We are finalizing our proposal that the Enabling Exchange Under TEFCA measure would be worth the total amount of points available for the Health Information Exchange Objective. We are finalizing our proposal in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28589 through 28591) to change the scoring methodology beginning with the EHR reporting period in CY 2023, such that the Health Information Exchange Objective would be worth no more than 30 points, therefore we are finalizing our proposal that the Enabling Exchange Under TEFCA measure would be worth 30 points. We are finalizing our proposal that eligible hospitals and CAHs would report the Enabling Exchange Under TEFCA measure by attestation, and that the measure would require a ''yes/no'' response. We are not finalizing our proposal that this measure be calculated by reviewing only the actions for patients whose records are maintained using CEHRT as calculations are not necessary for this measure, which instead requires attestation to the specified statements. We are finalizing our proposal that eligible hospitals and CAHs would attest to the following: Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) (in good standing that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy; and using the functions of CEHRT to support bi-directional exchange of patient information in production, under this Framework Agreement. We refer readers to the FY 2023 IPPS/LTCH PPS proposed rule for additional information on certified health IT capabilities that can support bi-directional exchange under a Framework Agreement (87 FR 28582 through 28585). Additionally, we are finalizing our proposal in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28593 through 28594) to remove associated regulatory text, therefore, we will not be updating 42 CFR 495.24(e) to reflect the addition of the Enabling Exchange Under TEFCA measure.

5. Public Health and Clinical Data Exchange Objective

a. Background

The Medicare Promoting Interoperability Program for eligible hospitals and CAHs has been an important mechanism for encouraging healthcare data exchange for public health purposes through the Public Health and Clinical Data Exchange Objective. Effective responses to public health events, such as the COVID–19 PHE, require fast, accurate exchange of data between health care providers and Federal, state, and local public health agencies (PHAs). Health care providers collect these data for patient care, and PHAs need them to protect the public, whether to track an outbreak, initiate contact tracing, find gaps in vaccine coverage, or pinpoint the source of a foodborne outbreak.

There are six measures under the Public Health and Clinical Data Exchange Objective: Immunization Registry Reporting, Syndromic Surveillance Reporting, Electronic Case Reporting, Electronic Reportable Laboratory (ELR) Result Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting. For background on this objective and its associated measures, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41665 through 41667), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45470 through 45479). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45470 through 45479), we finalized the requirement for eligible hospitals and CAHs to report four of the six of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the EHR reporting period in CY 2022: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. These four measures will put PHAs on better footing for future health threats and a long-term COVID–19 pandemic recovery by strengthening three important public health functions: (1) early warning surveillance, (2) case surveillance, and (3) vaccine uptake. Requiring these measures will enable nationwide

syndromic surveillance for early warning of emerging outbreaks and threats; automated case and laboratory reporting for fast public health response; and local and national visibility on immunization uptake so PHAs can tailor vaccine distribution strategies.

b. Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective: Antimicrobial Use and Resistance (AUR) Surveillance Measure

Antimicrobial-resistant (AR) infections are caused by pathogens that no longer respond to the drugs designed to kill them and directly threaten patient and population health. An effective national response to the threat presented by antimicrobial resistant bacteria requires robust systems for systematically collecting, analyzing, and using antimicrobial use and resistance data to direct action.

Each year in the United States, more than three million people are infected by an antimicrobial-resistant pathogen or *C. difficile* (an opportunistic pathogen associated with antimicrobial use), and nearly 50,000 people die.[1129] As more pathogens become resistant to available antimicrobials, options for reliably and rapidly treating infections—including pneumonias, foodborne illnesses, and healthcare-associated infections—become increasingly limited, more expensive and, in some cases, nonexistent. The CDC has found that one-third to one-half of all antimicrobials used in inpatient and outpatient settings are either unnecessary or prescribed incorrectly.[1130] The misuse and overuse of antimicrobials both facilitates the emergence of drug-resistant pathogens and exposes patients to needless risk for adverse effects. AR infections can also complicate the response to and recovery from other serious health risks, such as COVID–19. Rates of AR infections have increased in healthcare settings since the beginning of the COVID–19 pandemic, reversing previous prevention successes such as declines of AR infections by as much as 30 percent prior to the pandemic.[1131] Additionally, Methicillin-resistant *Staphylococcus aureus* (MRSA) infections increased five consecutive quarters from 2020 to 2021, including some quarter over quarter increases of 39 percent.[1132] Strengthening of infection prevention and control and antibiotic stewardship is needed to address these challenges and ensure a solid foundation for future public health emergencies.

As outlined in the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), 2020–2025,[1133] an effective national response to the threat presented by AR bacteria and fungi depends in part on slowing the emergence of new resistant threats and preventing the spread of existing resistant infections. Successfully meeting this goal, in turn, requires robust systems for collecting, analyzing, and using AUR data to direct action. Systematically collecting AUR data also helps inform the availability and potential need for new antibiotics to address emerging forms of resistance.

Antimicrobial use (AU) data delivered to antimicrobial stewardship programs (ASPs) enable stewards to develop, select, and assess interventions aimed at optimizing antimicrobial prescribing. These interventions, in turn, serve to improve antimicrobial treatment effectiveness, protect patients from harms caused by unnecessary antimicrobial exposure, and curb antimicrobial resistance associated with prophylactic and therapeutic excess. Studies have shown that ASPs can help slow the emergence of antimicrobial resistance while optimizing treatment and minimizing costs—all in support of safe and appropriate care for patients.

Antimicrobial resistance data can aid in clinical decision making (hospital cumulative antibiograms) and direct transmission prevention and antimicrobial stewardship efforts. With timely and complete reporting, these data can also facilitate rapid identification and control of potential outbreaks, as well as longer term assessment of progression or improvement to guide public health response efforts. Currently, acute care hospitals and CAHs voluntarily report to CDC's National Healthcare Safety Network's (NHSN) AUR Module with approximately 2000 eligible hospitals and 1000 CAHS reporting on AUR NHSN. Compared to the hospitals that have not reported AUR data, those that reported were more likely to be larger and teaching hospitals.

The extensive voluntary participation in NHSN's AUR surveillance, which calls for hospitals to buy or build an AUR reporting solution, indicates that thousands of hospitals see value in NHSN's AUR surveillance. However, incomplete participation in NHSN's AUR surveillance limits the generalizability of the AUR data: The data are subject to selection bias and do not provide a comprehensive national picture. Other comparable NHSN reporting pathways—such as those used to report data on blood stream infections, urinary tract infections, and other healthcare-associated infections—are required under CMS quality reporting and value-based payment programs, including the Hospital Value-Based Purchasing (VBP) and Hospital-Acquired Condition (HAC) Reduction Programs. In the Hospital VBP and HAC Reduction Programs, the reporting coverage and compliance with NHSN measures is routinely approximately 97 percent. The benefits of monitoring AUR data for patient care and public health are most likely to be achieved when data collection and analysis are systematic, standardized, and achieve complete coverage across eligible facilities. In fact, as more hospitals participate, the system becomes better at detecting emerging threats as the network for data collection grows.

We believe that requiring an AUR measure under the Medicare Promoting Interoperability Program would enable the development of a true national picture of the threat posed by antimicrobial overuse and resistance. Requiring AUR reporting through CDC's NHSN would produce inpatient AU and AR benchmarks that can be used to guide clinical and public health action and enable a true national picture of the threat posed by antimicrobial overuse and resistance. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28586 through 28587), we proposed the following new AUR Surveillance measure under the Public Health and Clinical Data Exchange Objective:

AUR Surveillance measure: The eligible hospital or CAH is in active engagement with CDC's National Healthcare Safety Network (NHSN) to submit antimicrobial use and resistance (AUR) data for the EHR reporting period and receives a report from NHSN indicating their successful submission of AUR data for the EHR reporting period.

We proposed to require eligible hospitals and CAHs to report this

[1129] CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.

[1130] CDC. Antibiotic Use in the United States, 2018 Update: Progress and Opportunities. Atlanta, GA: US Department of Health and Human Services, CDC; 2019.

[1131] CDC. 2020 National and State Healthcare-Associated Infections Progress Report. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2021.

[1132] Weiner-Lastinger, Lindsey M., et al. ''The Impact of Coronavirus Disease 2019 (COVID–19) on Healthcare-Associated Infections in 2020: A Summary of Data Reported to the National Healthcare Safety Network.'' *Infection Control & Hospital Epidemiology,* vol. 43, no. 1, 2022, pp. 12–25., doi:10.1017/ice.2021.362.

[1133] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2020). National Action Plan for Combatting Antibiotic-Resistant Bacteria, 2020–2025. Available at: *https://aspe.hhs.gov/reports/national-action-plan-combating-antibiotic-resistant-bacteria-2020-2025*.

measure beginning with the EHR reporting period in CY 2023. Eligible hospitals and CAHs that report a ''yes'' response or an exclusion for which they are eligible would receive credit for reporting the measure. Eligible hospitals and CAHs that report a ''no'' response or fail to report any response would not receive credit for reporting the measure and would fail to satisfy the Public Health and Clinical Data Exchange Objective. No additional points would be associated with the reporting of this measure, but it would be one of five required measures required to satisfy the Public Health and Clinical Data Exchange Objective. See the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28589) for further detail on the proposals and section IX.H.6 of this final rule for the finalized modification of the scoring of this objective.

For purposes of this proposed measure, we proposed eligible hospitals and CAHs must use technology certified to the criterion at 45 CFR 170.315(f)(6), ''Transmission to public health agencies—antimicrobial use and resistance reporting.'' We also stated we were aware of an updated version of the standard referenced in the criterion [1134] and that we would work with our partners at CDC and ONC to consider avenues for addressing use of this specification within the ONC Health IT Certification program. We provide additional information on use of this updated version below.

We proposed three exclusions for the AUR Surveillance measure as follows: the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have electronic medication administration records (eMAR)/barcoded medication administration (BCMA) records or an electronic admission discharge transfer (ADT) system during the EHR reporting period; or (3) Does not have an electronic laboratory information system (LIS) or electronic ADT system during the EHR reporting period (87 FR 28587). We anticipate reevaluating exclusions #2 and #3 for future EHR reporting periods. The AUR Surveillance measure would leverage the standards and functionality included in certified technology referenced under the CEHRT definition, including the ability to transmit to PHAs for antimicrobial use and resistance reporting.

We invited public comment on these proposals. We also invited comments on the feasibility of the timeline and any additional exclusions that we should consider for this measure for proposal in future rulemaking.

Comment: Many commenters supported the proposal to add the AUR Surveillance measure agreeing on the critical role this measure would play in improving antibiotic use and reducing antibiotic resistance, facilitating targeting areas for improvement, providing data critical to tracking threats and identifying trends nationwide, informing clinicians, public health agencies, government, and policymakers alike. Several commenters noted the importance of this measure to provide a much needed national, generalizable comparison and benchmarks. A few commenters noted the utility of this data to potentially drive increased investment from Congress to address the rising threat of adverse events such as antibiotic resistance.

Response: We appreciate commenters' support of the proposal to require the AUR Surveillance measure under the Public Health and Clinical Data Exchange Objective. We believe that this measure will help produce inpatient AU and AR benchmarks that can be used to guide clinical and public health action and enable a true national picture of the threat posed by antimicrobial overuse and resistance.

Comment: Many commenters did not support the proposal to add the AUR Surveillance measure. Several commenters stated that the implementation timeline was too ambitious and that the financial burden on health care providers was substantial. A commenter pointed out that it is already too late to include this in the budget for CY 2023 which has, at the time of the FY 2023 IPPS/LTCH PPS proposed rule being published, already been approved. A few commenters highlighted that the majority of CAHs will not be ready and thus find themselves at a substantial disadvantage. A few commenters noted that eligible hospitals are still dealing with burden related to the PHE and these proposals overwhelm systems already tasked with substantial COVID–19 related reporting and clinical requirements. Many commenters offered recommendations to delay the adoption of the AUR Surveillance measure to the Public Health and Data Exchange Objective with most recommending a delay of at least one year and several recommending alternative periods of delay. A commenter requested that the adoption of the measure be delayed until CEHRT criteria are adopted and vendors and hospitals have sufficient time to implement the CEHRT criteria. A few commenters requested adoption be delayed until the end of the PHE. Several commenters recommend making the measure optional to allow time for implementation. A commenter noted that smaller and resource-limited facilities may need a phase in time not to exceed two years and another commenter recommended a phase-in time with stronger incentives.

Response: We thank the commenters for their feedback. We believe that the AUR Surveillance measure is critical to stem AR infections nationwide, by providing the necessary AUR data to direct action. However, we also heard very clearly from commenters that eligible hospitals and CAHs continue to face enormous operational challenges as a result of the ongoing PHE.

We understand that many commenters believe that more time may be needed for health care providers and EHR vendors to implement the necessary changes in workflows, infrastructure and functionality to report the AUR Surveillance measure. We recognize more time may be beneficial for eligible hospitals and CAHs to implement the necessary infrastructure. Therefore, we are delaying our adoption of this measure by one year, so that it will be included in the Public Health and Clinical Data Exchange Objective and will be a required measure beginning with the EHR reporting period in CY 2024. Regarding the concern over a lack of applicable certification criteria referenced in the CEHRT definition, we inform readers that the applicable criteria is available in ''Transmission to public health agencies—antimicrobial use and resistance reporting'' in 45 CFR 170.315(f)(6), and was finalized in the ''2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' final rule published on October 16, 2015 (80 FR 62668).

Comment: A few commenters recommended adding exceptions for hospitals when they encounter situations related to bi-directional exchange that are outside their control such as encountering deficiencies in the state/local public health agency. A commenter recommended adding an exclusion for eligible hospitals and CAHs using CEHRT that does not include technology certified per § 170.315(f)(6) at the beginning of the EHR reporting period. This type of exclusion would be similar to the one year exclusion that is available for MIPS eligible clinicians for the Electronic Case Reporting measure under the

[1134] *https://www.hl7.org/implement/standards/product_brief.cfm?product_id=426.*

Public Health and Clinical Data Exchange Objective for those clinicians in CY 2022 using CEHRT that does not include technology certified to the electronic case reporting certification criterion. Some commenters expressed concern that their ability to successfully fulfill this measure is limited based on dependence their health IT vendor team, and potentially by delays at the state level.

Response: We thank commenters for their feedback.

We do not believe that additional exclusions related to state and local readiness to engage in bi-directional exchange are necessary, as data within the AUR measure are reported directly to CDC through NHSN. We believe that granting eligible hospitals and CAHs an additional year to prepare to report on this measure will alleviate the concerns that the commenters have raised. Any health IT vendors that have not yet certified under 45 CFR 170.315(f)(6) ''Transmission to public health agencies—antimicrobial use and resistance reporting,'' will have sufficient time to update their product and complete certification due to the one year delay.

Comment: A few commenters requested clarification around the specific standards submitters are required to use, additional information on a minimum period for hospitals to transmit data, and technical assistance and support during the implementation period.

Response: As noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28587), for purposes of this measure, we proposed that eligible hospitals and CAHs must use technology certified to the criterion at 45 CFR 170.315(f)(6), ''Transmission to public health agencies—antimicrobial use and resistance reporting.'' This certification criterion references the ''HL7® Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection (HAI) Reports, Release 1, U.S. Realm, August 2013'' implementation specification, adopted at § 170.205(r)(1).

We note that an updated version of this this implementation specification has been approved under ONC's Standards Version Advancement Process. The Standards Version Advancement Process (SVAP) permits health IT developers to voluntarily update health IT products certified under the ONC Health IT Certification Program to newer versions of adopted standards and implementation specifications (85 FR 25775). Specifically, as part of the 2022 SVAP cycle, ONC has approved the use of ''HL7 CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3—US Realm, December 2020'' for the ''Transmission to public health agencies—antimicrobial use and resistance reporting'' at 45 CFR 170.315(f)(6). Health IT developers may begin voluntarily incorporating this specification into Certified Health IT Modules beginning August 29, 2022.

Our experience with NHSN has shown that reporting is not just broadly feasible but also highly valuable for hospitals and their state/local public health partners. As previously noted, over 2000 hospitals currently submit AU and/or AR data through CDC's NHSN. Eligible hospitals and CAHs that do encounter challenges submitting, reviewing, interpreting and using their AU and AR data have access to a robust suite of training and technical assistance resources, as well as one-on-one assistance from subject matter experts via a help desk system. NHSN gives eligible hospitals and CAHs the ability to see and analyze their data in real-time, as well as share that information with clinicians and facility leadership, as well as with other facilities (for example, a multi-hospital system) and partners such as health departments or quality improvement organizations. The measure must be fulfilled during the eligible hospital or CAH's EHR reporting period but it is hoped that once they are able to submit data that they will do so throughout the year.

Comment: Several commenters offered suggestions to support health care provider implementation and reduce participant burden associated with validation. A commenter recommended NHSN and CMS validation reports be aligned to reduce burden on health care providers. A commenter recommended that RxNorm codes be used. Finally, a commenter recommended that CMS allow health care providers to alternatively report on any 5 of the 7 available measures in the Public Health and Clinical Data Exchange Objective to achieve the 10 points.

Response: We thank them for their comments and agree with the importance of ensuring eligible hospitals and CAHs have the resources and support they need to meet requirements without undue reporting burden. CDC already offers a wide array of tools and resources to support onboarding, testing and validation, and data submission (see *https://www.cdc.gov/nhsn/pdfs/cda/PHDI-Facility-Guidance-508.pdf*). And CDC and CMS will work together to build upon these resources as needed to support health care provider participation. Similarly, CDC and CMS will work together to align and streamline accountability processes (for example, reporting validation; (letters from the NHSN to the hospitals to serve as proof of their active engagement). With respect to the commenter's suggestion that the AUR measure support the use of RxNorm codes, the CDC has confirmed that the measure already does so. Finally, as we have previously discussed, we believe that requiring reporting for specific measures under the Public Health and Clinical Data Exchange objective is necessary to better prepare for and support public health responses to health threats. For a thorough discussion of our reasoning for selecting each required measure we refer readers to the FY 2022 IPPS/LTCH final rule (86 FR 45470 through 45479).

After consideration of the public comments we received, we are finalizing our proposal to require eligible hospitals and CAHs to report the AUR surveillance measure, with the modification that it will be required beginning with the EHR reporting period in CY 2024. Eligible hospitals and CAHs that report a ''yes'' response or an exclusion for which they are eligible will receive credit for reporting the measure. Eligible hospitals and CAHs must use technology certified to the criterion at 45 CFR 170.315(f)(6), ''Transmission to public health agencies—antimicrobial use and resistance reporting.'' We are adopting three exclusions as proposed for the AUR Surveillance measure as follows: the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have electronic medication administration records (eMAR)/barcoded medication administration (BCMA) records or an electronic admission discharge transfer (ADT) system during the EHR reporting period; or (3) Does not have an electronic laboratory information system (LIS) or electronic ADT system during the EHR reporting period.

c. Revisions to Active Engagement

(1) Background

The Medicare Promoting Interoperability Program has been an important mechanism for encouraging data exchange between health care providers and PHAs through the Public Health and Clinical Data Exchange Objective. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45470 through 45479), we finalized beginning with the EHR reporting period in CY 2022, eligible hospitals and CAHs must report

on the four required measures to obtain points under the Public Health and Clinical Data Exchange Objective: (1) Syndromic Surveillance Reporting; (2) Immunization Registry Reporting; (3) Electronic Case Reporting; and, (4) Electronic Reportable Laboratory Result Reporting. We believe these required measures will motivate health IT vendors to implement the necessary capabilities in their products and encourage eligible hospitals and CAHs to engage in the reporting activities described in the measures.

Despite these gains, ensuring the nation's thousands of hospitals implement and initiate data production for these vital public health capabilities remains an ongoing and important effort. The Medicare Promoting Interoperability Program provides an opportunity to continue strengthening the incentives for eligible hospitals and CAHs to engage in these essential reporting activities. Without adequate incentives, it will be difficult to attain the comprehensive data exchange needed to ensure fast, complete, actionable data in response to future public health threats.

In the EHR Incentive Program Stage 3 final rule (80 FR 62862 through 62864), beginning with the EHR reporting period in 2016, we established a definition for active engagement under the Public Health and Clinical Data Registry Reporting Objective. Active engagement is defined as when an eligible hospital or CAH is in the process of moving towards sending ''production data'' to a public health agency or clinical data registry, or is sending production data to a public health agency or clinical data registry. We noted that the term ''production data'' refers to data generated through clinical processes involving patient care and it is used to distinguish between this data and ''test data'' which may be submitted for the purposes of enrolling in and testing electronic data transfers. We established the following three options for eligible hospitals and CAHs to demonstrate active engagement:

Option 1—Completed registration to submit data: The eligible hospital or CAH registered to submit data with the PHA or, where applicable, the clinical data registry (CDR) to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the eligible hospital or CAH is awaiting an invitation from the PHA or CDR to begin testing and validation. Eligible hospitals or CAHs that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.

Option 2—Testing and validation: The eligible hospital or CAH is in the process of testing and validation of the electronic submission of data. Eligible hospitals or CAHs must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that health care provider not meeting the measure.

Option 3—Production: The eligible hospital or CAH has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR. For more information about the current options for active engagement, we refer readers to the EHR Incentive Program Stage 3 final rule (80 FR 62862 through 62864).

(2) Revision to Options for Active Engagement

The three active engagement options provided flexibility for eligible hospitals and CAHs to meet the measures under the Public Health and Clinical Data Exchange Objective in a variety of ways, but they did not provide an incentive to move through the options and get to option 3, production, where there is the ongoing electronic submission of data. Option 1, completed registration to submit data, was an important option in 2016 as many PHAs and CDRs were starting to come online, and thus the provision of this option recognized that many eligible hospitals and CAHs were just beginning to engage in electronic data exchange with PHAs and CDRs. Now many years have passed, and we believe that eligible hospitals and CAHs have had ample time to complete option 1.

Thus, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28588), we proposed to consolidate current options 1 and 2 into one option beginning with the EHR reporting period in CY 2023. We did not propose any substantive changes to the individual options or requirements for selecting the individual options; rather, we would combine current options 1 and 2 into a single option, as follows:

1. Proposed Option 1. Pre-production and Validation (a combination of current option 1, completed registration to submit data, and current option 2, testing and validation);

2. Proposed Option 2. Validated Data Production (current option 3, production).

Eligible hospitals and CAHs must demonstrate their level of active engagement as either proposed Option 1 (pre-production and validation) or proposed Option 2 (validated data production) to fulfill each measure. We invited public comment on these proposed changes to the options for active engagement.

Comment: Many commenters supported the proposal to modify the active engagement options under the Public Health and Clinical Data Exchange Objective.

Response: We thank commenters for their support of our proposal to modify the options of active engagement under the Public Health and Clinical Data Exchange Objective.

Comment: A commenter requested clarification on the consolidation of options 1 and 2 for the levels of active engagement with regard to eligible hospitals and CAHs that have completed registration but not yet begun testing and validation.

Response: The proposed active engagement option 1: Pre-Production and Validation includes both the completion of registration to submit data with the PHA or CDR, as applicable, and being in the process of testing and validation of the electronic submission of data. Upon receiving an invitation from the PHA or CDR to begin testing and validation, the eligible hospital or CAH should begin testing and validation, as we understand the validation process can take some time. If, at any point in the process, an eligible hospital or CAH encounters a lack of readiness on the part of the PHA or CDR, the eligible hospital or CAH could consider whether it could report an exclusion for one or more of the measures associated with the Public Health and Clinical Data Exchange Objective.

Comment: A few commenters expressed concern that eligible hospitals and CAHs are determining their active engagement status without input from the appropriate public health agency. These commenters requested that CMS provide further guidance to define the active engagement option 2 criteria, and identify at what point an eligible hospital or CAH can move from active engagement option 1 to active engagement option 2.

Response: To move from Active Engagement Option 1: Pre-production and Validation, to Active Engagement Option 2: Validated Data Production, the eligible hospital or CAH must finish validation. Validation is an effort to ensure that the data exchanged with a public health agency is high quality and useful, and meets the appropriate HL7 implementation guide standard. Only the PHA or CDR can confirm validation

has been completed and a ''production'' state has been reached.

Comment: Several commenters did not support the proposal, stating that the reduction of levels obscures the necessary granularity of where hospitals are in the onboarding process. The commenters stated that since eligible hospitals and CAHs do not control the onboarding process, and that this varies based on the resources at the public health departments, it is important to distinguish between those who are waiting to begin testing and validation from those who are actively engaged in testing and validation.

Response: CMS does not agree that it is important to differentiate between those who are registered and those who have begun testing and validation. CMS has collaborated with the PHA community and has received comments that PHAs currently do not have any waitlists, and the eligible hospitals or CAHs who register are immediately invited to begin testing and validation. CMS agrees that eligible hospitals and CAHs should not be held accountable for actions outside of their control. However, at this time, registration is no longer a meaningful status, as PHAs are ready to begin testing and validation with those who register right away. CMS is not concerned with the loss of granularity, and we believe that this will facilitate easier reporting from our partners.

Additionally, we do not believe that allowing eligible hospitals and CAHs to remain at the registration stage fulfills the intent of the public health measures. Validation is critical as it ensures that the data from eligible hospitals and CAHs meets the needs of public health for both routine and emergency reporting. This is true across the Electronic Case Reporting measure, the Electronic Reportable Laboratory Result Reporting measure, the Syndromic Surveillance Reporting measure, the Immunization Registry Reporting measure, and in the future, the AUR Surveillance measure. In addition, public health capabilities for onboarding may have been delayed at the state level due to the COVID–19 pandemic. As such, CDC is providing funding for PHAs to improve and modernize their data infrastructure, which will result in more rapid testing and validation.

After consideration of the public comments we received, we are finalizing our proposal to consolidate current options 1 and 2 into a new combined option called Pre-production and Validation and renaming the current option 3 as Validated Data Production beginning with EHR reporting periods in CY 2023. Our goal continues to be that all eligible hospitals and CAHs will be at the Validated Data Production option as successful exchange of data is needed because that is where that data can be utilized to combat current and future PHEs.

(3) Reporting Requirement for Level of Engagement

Although we established the active engagement options, eligible hospitals and CAHs currently are not required to report their level of active engagement for any of the measures associated with the Public Health and Clinical Data Exchange Objective. During the recent COVID–19 PHE, we recognized the importance of public health reporting, as discussed further in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28585 through 28586), and we believe that knowing the level of active engagement that an eligible hospital or CAH selects would provide information on the types of registries and geographic areas with health care providers in the Pre-production and Validation stage. Our goal is for all health care providers nationwide to be at the Validated Data Production stage so that data will be actively flowing and public health threats can be monitored. Therefore, as proposed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28588), for the Public Health and Clinical Data Exchange Objective, in addition to submitting responses for the required measures and any optional measures an eligible hospital or CAH chooses to report, we proposed to require eligible hospitals and CAHs to submit their level of active engagement, either Pre-production and Validation or Validated Data Production) for each measure they report beginning with the EHR reporting period in CY 2023. We believe that this information regarding the level of active engagement would be helpful as it would enable HHS to identify registries and PHAs which may be having difficulty onboarding eligible hospitals and CAHs and moving them to the Validated Data Production level. If we can identify the PHAs with which eligible hospitals and CAHs are encountering difficulties, we believe we will be able to identify the barriers that prevent them from moving to the Validated Data Production level and work to develop solutions to overcome the barriers.

We invited public comment on the proposal to require submission of the level of active engagement.

Comment: Many commenters supported the proposal to require eligible hospitals and CAHs to report level of active engagement on measures in the Public Health and Clinical Data Exchange Objective. Many commenters cited that bi-directional data exchange is integral to achieve meaningful impacts in health care delivery and the importance of reporting the level of active engagement to promote transparency of active engagement status at a national level.

Response: We thank the commenters for their support of our proposal to require eligible hospitals and CAHs to report their level of active engagement on measures in the Public Health and Clinical Data Exchange Objective. We agree with commenters that bi-directional data exchange is integral in health care delivery.

Comment: A commenter requested that hospitals be required to provide proof from a public health agency of their active engagement status through a letter or other forms of acknowledgement as through HL7 messages and emails indicating confirmation.

Response: At this time, eligible hospitals and CAHs attest to CMS. PHAs have no role in the attestation process. Many eligible hospitals and CAHs request documentation from the PHA to support their active engagement status, which is used in case of an audit by CMS. CMS agrees that this is a best practice. CMS does acknowledge the desire of PHAs to become more engaged in the attestation process for eligible hospitals and CAHs but to date we have not established what that relationship might be. However, eligible hospitals and CAHs will be required to report their level of active engagement for the first time. If CMS learns that there is a mismatch between the active engagement records at PHAs and the active engagement status provided through attestation, CMS may consider making a future change to the attestation process. No change will be made until CMS has more evidence about eligible hospitals' and CAHs' self-reported active engagement status.

Comment: A few commenters did not support the proposal to require reporting the Active Engagement option selected under the Public Health and Clinical Data Exchange Objective and requested this not be required until the technology can facilitate the reporting. Some raised concerns that PHAs may not be able to offer documentation of level of active engagement in a reasonable amount of time to support compliance with a 90-day reporting period. Commenters also recommended active engagement be demonstrated with information provided either by the eligible hospital or CAH, or the PHA, or that CMS incentivize PHAs to turn

around this information in a timely manner. A few commenters requested that CMS provide further guidance illustrating expectations for completion of active engagement options and how eligible hospitals and CAHs can prove their active engagement status. A commenter requested that CMS allow eligible hospitals and CAHs at least one year of stable reporting of public health measures without implementing this active engagement reporting requirement. Many commenters supported an exclusion for situations in which the state or public health department has not declared readiness or lacks resources for timely onboarding.

Response: We acknowledge commenters' concerns regarding our proposal to require eligible hospitals and CAHs to report their level of active engagement for each Public Health and Clinical Data Exchange measure. However, we believe that this information will be extremely valuable to better understand progress with reporting over time and readiness for public health emergencies.

We offer the following examples as ways an eligible hospital or CAH may demonstrate their level of active engagement:

- A dated report or screenshot from CEHRT that documents successful submission to the registry or PHA. The report should include evidence to support that it was generated for that eligible hospital's or CAH's system (for example, identified by CMS certification number [CCN] and eligible hospital or CAH) name or;
- A dated report or screenshot of successful registration or electronic transmission (for example, screenshot from another system, etc.). The report should include evidence to support that it was generated for that eligible hospital or CAH (for example, identified by CMS certification number [CCN] and eligible hospital or CAH name) or;
- A letter or email from a registry or PHA confirming registration.

With respect to the recommendation to include an exclusion, we refer readers to the existing exclusions for each measure within the Public Health and Clinical Data Exchange Objective (See Table IX.H.-07.). For instances when there is an issue with the ability of a PHA or CDR to receive the data in the specific standards required to meet the CEHRT definition or where no PHA has declared readiness to receive data from eligible hospitals or CAHs, there are exclusions available for eligible hospitals and CAHs (42 CFR 495.24 (e)(8)(iii)). While we recognize that there may be variability in ability to quickly test and validate state to state, PHAs have been requiring transmission of electronic laboratory reporting, immunization registry reporting, and syndromic surveillance reporting for many years. To help address the existing variability, CDC is providing funding for PHAs to improve and modernize their data infrastructure, which will result in more rapid testing and validation. In addition, most eligible hospitals and CAHs are successfully reporting these measures.

Comment: A few commenters requested that CMS provide further guidance on whether the previous EHR Incentive Program registration satisfies current program requirements. A few commenters requested that CMS address concerns over lack of vendor readiness. A few commenters requested that CMS provide more clarity on how active engagement status is impacted by eligible hospitals and CAHs that registered with PHAs in the past but will only now be engaging in data exchange with the PHA.

Response: If an eligible hospital or CAH has previously registered and has not received an invitation to proceed to testing and validation, we recommend that they reach out to the PHA to confirm that they remain actively engaged and to discuss their timeline for moving into testing and validation.

After consideration of the public comments we received, we are finalizing our proposal for the Public Health and Clinical Data Exchange Objective to require that in addition to submitting responses for the required measures and any optional measures an eligible hospital or CAH chooses to report, that they submit their level of active engagement, either Option 1: Pre-production and Validation or Option 2: Validated Data Production (as finalized in section H.5.c(2)), for each measure they report beginning with the EHR reporting period in CY 2023.

(4) Changes to the Duration of Active Engagement Options

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28588), eligible hospitals and CAHs currently are not required to report their level of active engagement, or advance from one option to the next option within a certain period of time. As we proposed requiring eligible hospitals and CAHs to submit their level of active engagement for each measure they report, we also proposed, beginning with the EHR reporting period in CY 2023, that eligible hospitals and CAHs may spend only one EHR reporting period at the Option 1: Pre-production and Validation level of active engagement per measure, and that they must progress to the Option 2: Validated Data Production level for the next EHR reporting period for which they report a particular measure. For example, under this proposal, if an eligible hospital or CAH submits a level of active engagement at the proposed option 1 level (Pre-production and Validation) for the Syndromic Surveillance Reporting measure for the EHR reporting period in CY 2023, the eligible hospital must report a level of active engagement at the proposed option 2 level (Validated Data Production) for the next EHR reporting period for which it reports the Syndromic Surveillance Reporting measure, or it would fail to satisfy the Public Health and Clinical Data Exchange Objective for its next EHR reporting period. The options for active engagement assume the same PHA or CDR is used by the hospital. In the event an eligible hospital or CAH chooses to switch between one or more CDRs or PHAs, we proposed they would be permitted to spend an additional EHR reporting period at the Option 1: Pre-production and Validation level to assist with onboarding to the new CDR or PHA. As electronic transmission of high-quality data is achieved at the Option 2: Validated Data Production level, we want all eligible hospitals and CAHs to reach this level.

We invited public comments on these proposed changes to the duration of the active engagement options.

Comment: Many commenters supported the proposal to limit the amount of time an eligible hospital or CAH may spend at the pre-production and validation level of active engagement to one EHR reporting period. Many commenters noted the importance of eligible hospitals and CAHs exchanging data with public health agencies, as highlighted by the COVID–19 PHE, as well as how this limit on duration in the pre-production and validation level promotes and incentivizes progress through the levels of active engagement and data exchange.

Response: We thank the commenters for their support of our proposal to limit the amount of time an eligible hospital or CAH may spend in the pre-production and validation level of active engagement. We agree on the importance of data exchange between eligible hospitals and public health agencies and clinical registries, particularly in light of the ongoing COVID–19 PHE, and thus have prioritized efforts to promote data exchange with public health agencies and clinical registries.

Comment: While offering support, several commenters expressed concern

about the readiness of state and local public health agencies and registries to accept production data and urged CMS to implement changes to the duration of active engagement levels in a phased approach or offer exclusions for circumstances that are out of the control of the eligible hospital or CAH.

Response: We appreciate commenters' recommendations regarding including exclusions for when state and local jurisdictions may not be ready or capable of accepting production data, or are slow to onboard, and refer readers to the existing exclusions for each Public Health and Clinical Data Exchange measure. For instance, when there is an issue with the ability of a PHA or CDR to receive the data in the specific standards required to meet the CEHRT definition or where no PHA has declared readiness to receive data from eligible hospitals or CAHs, there are exclusions available for eligible hospitals and CAHs (42 CFR 495.24 (e)(8)(iii)).

Comment: Many commenters did not support the proposal to limit the duration of Pre-production and Validation level of active engagement to one EHR reporting period citing that progression out of this level is often not under hospital control and depends on the resources available from a given PHA and their technical capabilities and timeliness in communications. A few commenters recommended adding an exclusion to allow for when public health agencies have limited resources to validate and onboard. A few commenters suggested this could lead to rushed validation and poor data quality, particularly with a move to a 180-day EHR reporting period. A few commenters stated concerns that EHR vendors may not be ready for testing in 2023 or 2024 and suggested CMS allow hospitals multiple reporting years under the Pre-Production and Validation level. A commenter requested that CMS allow hospitals at least one year of stable reporting of public health measures without implementing this active engagement reporting requirement. Another commenter did not support the proposal because the commenter stated CMS lacks a baseline as it has never collected eligible hospitals or CAHs active engagement level.

Response: We acknowledge commenters' concerns regarding the lack of control that eligible hospitals or CAHs may have when moving through the levels of active engagement. In particular, we recognize that an eligible hospital's or CAH's successful progression through the levels of active engagement is partially dependent on the readiness, resources, and technical capabilities of the PHAs to which it reports. We further recognize that public health capacity remains somewhat variable and constrained—particularly as PHAs continue to direct substantial resources to the COVID–19 PHE response efforts. Accordingly, we agree with the commenter who suggested allowing at least one year of stable reporting of public health measures before instituting limits on the length of time eligible hospitals and CAHs can spend in the pre-production and validation level of active engagement.

For these reasons, we are delaying the implementation of this requirement by one year, such that it will apply beginning with the EHR reporting period in CY 2024. This delay balances the urgent need to move eligible hospitals and CAHs into data production with the need identified by the commenters for additional time for public health agencies and health care providers to prepare for this change. Without this requirement, facilities can linger in registration, testing or validation for years, which provides little benefit to the public in a PHE or to address health threats. Moreover, existing data PHAs have shared with CDC indicate that registration, testing and validation completion rates are already fairly rapid—typically less than 3 months in many cases. Admittedly, there are exceptions—in particular, the validation stage can take longer, as it depends on PHA readiness, as well as the quality of the data a provider is sending and the CEHRT product being used. However, we anticipate that testing and validation cycle times will continue to shrink over the next year as public health agencies use CDC funding to modernize their data infrastructures.

Nonetheless, we appreciate and agree with commenters' recommendations regarding the need for exclusions when state and local jurisdictions are not ready or capable of accepting production data, or are slow to onboard facilities (for example, an eligible hospital is unable to complete testing and validation in a single EHR reporting period because the PHA has a backlog of validation requests). We believe an eligible hospital or CAH could consider whether the existing exclusions for each measure associated with the Public Health and Clinical Data Exchange Objective could be claimed in these cases and refer readers to these exclusions at 42 CFR 495.24 (e)(8)(iii). However, we will continue to examine this issue in collaboration with CDC and, if additional exclusions are warranted, we may address them and any other changes warranted in future rulemaking.

Comment: A few commenters had questions regarding allowances for when hospitals need to migrate from testing/validation to production and back if the public health department performs systems updates, for unforeseen outages, or if hospitals move to a different vendor and their testing does not line up well to be in production during their next reporting period. A few commenters expressed concern over the lack of control hospitals have in moving from one level to another, or in receiving documentation that proves they have achieved a certain level of active engagement. A commenter requested that CMS work with other agencies to support state organizations in providing the technical support necessary and suggested including an exclusion for situations in which a state has limited capacity for engagement.

Response: We appreciate commenters' feedback on the proposal to limit the time spent in the Pre-production and Validation level of active engagement to one EHR reporting period. With respect to the concern about moving to different vendors, PHAs, or CDRs, the options for active engagement assume the same PHA or CDR is used by the hospital. In the event an eligible hospital or CAH chooses to switch between one or more CDRs or PHAs, we proposed they would be permitted to spend an additional EHR reporting period at the Pre-production and Validation level to assist with onboarding to the new CDR or PHA (87 FR 28588). As we have previously stated, we acknowledge commenters' concerns regarding the lack of control that eligible hospitals or CAHs may have when moving through the levels of active engagement and the dependency on resources and technical capabilities at public health departments and registries. We refer readers to the existing exclusions for each Public Health and Clinical Data Exchange measure. For instances when there is an issue with the ability of a PHA or CDR to receive the data in the specific standards required to meet the CEHRT definition or where no PHA has declared readiness to receive data from eligible hospitals or CAHs, there are exclusions available for eligible hospitals and CAHs (42 CFR 495.24 (e)(8)(iii)).

Comment: A commenter expressed concern for smaller hospitals who may need more time to progress to production and stated that establishing a time limit should be based on a solid understanding of the barriers hospitals face to moving between levels of active engagement. A commenter recommended that CMS incentivize

health care organizations (HCOs) and vendors to continue to engage with PHAs once initial validated production data are flowing to ensure that accurate, complete, and timely data for reportable conditions are available to PHAs as required by jurisdictional laws and regulations and for effective public health response activities. A commenter recommended CMS create a list of states where certain types of public health and clinical data exchange is immature to identify potential scoring issues.

Response: We appreciate commenters' feedback regarding the impact of this policy on smaller hospitals and recommendations to provide incentives for continued engagement with PHAs as well as developing resources to identify where public health and clinical data exchange is immature. We will monitor implementation and consider future changes if necessary.

Comment: Several commenters noted that local and state health departments have limitations and offer variable levels of technical capacity to support this type of data exchange and that CMS should follow and support development efforts at the state and local levels of PHAs and registries.

Response: We agree with the importance of ensuring health care providers and PHAs have the ability to set up data exchange within a reasonable timeframe. Our goal is that all parties continue to move towards validated production, which will prepare the nation for a more effective response to public health emergencies. As we discussed above, given the many challenges identified in the comments, we are delaying the implementation of this requirement until the beginning of the EHR reporting period in CY 2024.

Additionally, among the core objectives of CDC's DMI are seamless reporting to public health agencies and interoperability among core public health surveillance strategies. As such, CDC is providing funding to public health agencies to improve and modernize their data infrastructure. We are working closely with CDC to coordinate healthcare program requirements and public health modernization investments to foster co-maturation and readiness for bi-directional data exchange.

After consideration of the public comments we received, we are finalizing the proposals to limit the amount of time an eligible hospital or CAH may spend at the pre-production and validation level of active engagement to one EHR reporting period with the modification that this limitation will apply beginning with the EHR reporting period in CY 2024.

(5) Public Health Reporting and Information Blocking

The ONC 21st Century Cures Act final rule (85 FR 25642) implemented policies related to information blocking as authorized under section 4004 of the 21st Century Cures Act, as discussed further in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28588 through 28589).

6. Changes to Scoring Methodology for the EHR Reporting Period in CY 2023

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41645), we adopted a new performance-based scoring methodology for eligible hospitals and CAHs attesting under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019, which included a minimum scoring threshold of a total score of 50 points or more which eligible hospitals and CAHs must meet to satisfy the requirement to report on the objectives and measures of meaningful use under 42 CFR 495.24. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45491 through 45492), we increased the minimum scoring threshold from 50 points to 60 points beginning with the EHR reporting period in CY 2022. As shown in Table IX.H.-03, the points associated with the required measures sum to 100 points, and the optional measures may add additional bonus points. The scores for each of the measures are added together to calculate a total score of up to 100 possible points for each eligible hospital or CAH (83 FR 41636 through 41645). We note in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28589), we erroneously stated that we calculate a total score of up to 105 possible points, but we want to clarify that we cap the number of points at 100.

Table IX.H.–03 reflects the objectives and measures for the EHR reporting period in CY 2022 and was included in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45492).

TABLE IX.H.-03: PERFORMANCE-BASED SCORING METHODOLOGY EHR REPORTING PERIOD IN CY 2022

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 Points
	Bonus: Query of PDMP	10 points (*bonus*)*
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
	-OR-	
	Health Information Exchange Bi-Directional Exchange*	40 points*
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report the following four measures: * • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting	10 points
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (*bonus*)*

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. Electronic clinical quality measures (eCQM) measures are required, but will not be scored.
*Signifies a final policy adopted in the FY 2022 IPPS/LTCH PPS final rule.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28590), we noted that in proposing to make the Query of PDMP measure required, we would retain the 10 points associated with it, which are allocated as bonus points for the EHR reporting period in CY 2022. If finalized, we proposed to reduce the points associated with the Health Information Exchange Objective measures from the current 40 points to 30 points beginning with the CY 2023 EHR reporting period. The Public Health and Clinical Data Exchange Objective, with its current four required measures, is currently worth 10 points. Despite increasing the number of required measures from two to four to make the objective more effective in promoting public health data electronic exchange, the total number of points did not change between CY 2021 and CY 2022. We believe that increasing the point value of the Public Health and Clinical Data Exchange Objective would create a more meaningful incentive for eligible hospitals and CAHs to engage in the electronic reporting of public health information and recognize the importance of public health systems affirmed by the COVID–19 pandemic. Increasing the point value would make the Public Health and Clinical Data Exchange Objective a more central piece of the Promoting Interoperability Program, and better incentivize eligible hospitals and CAHs to implement these essential public health data exchange capabilities. Without adequate incentives, there remains a risk that eligible hospitals and CAHs will simply not prioritize implementing these capabilities, which are essential to ongoing efforts to address COVID–19 and will be indispensable for responding to future public health threats and emergencies. Increasing the point value would more appropriately incentivize eligible hospitals and CAHs to engage in the electronic reporting of public health information, and would align the value of the objective with the objective's importance and the effort necessary to meet the required measures.

Thus, we proposed to increase the points allocated to the Public Health and Clinical Data Exchange Objective from 10 to 25 points to better align with the true value of this objective beginning with the EHR reporting period in CY 2023. This proposal was independent of our proposal to add the AUR Surveillance measure to the objective, and we considered increasing the points regardless of whether the proposal to add the AUR Surveillance measure to the objective was finalized. We believe assigning 25 points to the objective reflects the importance of comprehensive, nationwide health care data exchange between eligible hospitals and CAHs and public health agencies. Nationwide health care data exchange would provide immense value to the public by improving the speed and effectiveness of public health responses, as well as to eligible hospitals and CAHs, since better public health response reduces pressure on hospitals, which can be overwhelmed in a public health crisis. To balance the increase in the points associated with the Public Health and Clinical Data Exchange Objective, we also proposed to reduce the points associated with the Provide Patients Electronic Access to Their Health Information measure from the current 40 points to 25 points beginning with the EHR reporting period in CY 2023.

We included Table IX.H.–04. in the FY 2023 IPPS/LTCH PPS proposed rule, which reflects the objectives, measures, and maximum points available for the EHR reporting period in CY 2023, if the proposals discussed (87 FR 28598) are finalized.

TABLE IX.H.-04: PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIOD IN CY 2023

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP*	10 points*	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points*	Required (eligible hospital or CAHs choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points*	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points*	
	-OR-		
	Enabling Exchange under TEFCA*	30 points*	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points*	Required
Public Health and Clinical Data Exchange	Report the following five measures:* • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting • AUR Surveillance Reporting*	25 points*	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (*bonus*)	Optional

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.

*Signifies a proposal made in the FY 2023 IPPS/LTCH PPS proposed rule.

The maximum points available in Table [IX.H.–04.] do not include the points that would be redistributed in the event an exclusion is claimed. For ease of reference, in the FY 2023 IPPS/LTCH PPS proposed rule, we included Table [IX.H.–054 at 87 FR 28592] which shows the point redistribution among the objectives and measures for the EHR reporting period in CY 2023 in the event an eligible hospital or CAH claims an exclusion, if the proposals made in the FY 2023 IPPS/LTCH PPS proposed rule are finalized.

TABLE IX.H.-05.: PROPOSED EXCLUSION REDISTRIBITION FOR EHR REPORTING PERIOD IN CY 2023

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE Objective
	Query of PDMP*	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	No exclusion
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	No exclusion
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under TEFCA*	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following five measures:* • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting • AUR Surveillance Reporting*	If an exclusion is claimed for each of the five measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.

*Signifies a proposal made in the FY 2023 IPPS/LTCH PPS proposed rule.

We invited public comment on these proposed changes to our scoring methodology.

Comment: A few commenters expressed support for the proposed changes to the scoring methodology. A commenter expressed support for increasing the points associated with the Electronic Prescribing Objective from 10 to 20 to further incentivize electronic prescribing. A few commenters supported the proposed reduction in points of the HIE Objective from 40 to 30 points. Many commenters supported the adjustment of the Public Health and Clinical Data Exchange Objective from 10 to 25 points. Several agreed with the importance of incentivizing efforts related to the COVID–19 pandemic.

Response: We thank the commenters for their support.

Comment: A few commenters did not support our proposal to reduce the number of points assigned to the HIE Objective citing that the current point allocation reflects the push for the continued adoption and expansion of clinical data exchange. A few commenters did not support the point reduction of the Provider to Patient Exchange Objective citing that such a reduction would signal that CMS devalues the exchange of data between patients and health care providers. A few commenters did not support our proposal to increase the total score of the Public Health and Clinical Data Exchange Objective citing the lack of readiness of, and variability among, states and public health agencies to receive and process data.

Response: We thank commenters for their concerns and feedback. Point changes across objectives reflect the importance of shifting priorities, especially during the COVID–19 pandemic. Thus we are reducing the points associated with the Provider to Patient Exchange Objective so we can increase the points associated with the Public Health and Clinical Data Exchange Objective due to the importance of public health data during PHEs. The reduction to the HIE Objective was to accommodate the requirement of the Query of PDMP measure which increased the points associated with the Electronic Prescribing Objective.

Comment: A commenter recommended increasing the number of points that hospitals can earn to accommodate the necessary point increases.

Response: While we appreciate this suggestion, we believe that increasing the number of points may inflate scores and would not reflect the priorities that are conveyed through the reallocation of points.

After consideration of the public comments we received, we are finalizing our proposals for changes to the scoring methodology for the EHR reporting period in CY 2023 without modification.

7. Public Reporting of Medicare Promoting Interoperability Program Data

Section 1886(n)(4)(B) of the Act requires the Secretary to post in an easily understandable format a list of the names and other relevant data, as determined appropriate by the Secretary, of eligible hospitals and CAHs who are meaningful EHR users under the Medicare FFS program, on a CMS website. In addition, that section requires the Secretary to ensure that an eligible hospital or CAH has the opportunity to review the other relevant data that are to be made public with respect to the eligible hospital or CAH prior to such data being made public.

As the Medicare Promoting Interoperability Program has evolved over the years, we have continued to expand the scope of relevant data points across the Medicare Promoting Interoperability Program. For example, we post information on a CMS website available to the public regarding those eligible hospitals and CAHs who attest to limiting or restricting the compatibility or interoperability of CEHRT under 42 CFR 495.40(b)(2)(i)(I), as established in the 2020 Patient Access and Interoperability final rule (85 FR 25578 through 25580). Additionally, in alignment with the Hospital IQR Program, we finalized proposals to begin publicly reporting eCQM data beginning with the CY 2021 reporting period, and subsequent years (85 FR 58975 through 58976).

To date, we have not publicly reported eligible hospitals' and CAHs' total scores for the Medicare Promoting Interoperability Program. We calculate a total score of up to 100 possible points by adding together the points earned for each required measure and any optional measures reported by an eligible hospital or CAH (83 FR 41636 through 41645). In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28592 through 28593), we proposed to post the eligible hospital's or CAH's actual score, up to 105 possible points, so that consumers can clearly see the high performing hospitals. We wish to clarify in this final rule that although we cap the total score at 100 points, the actual score includes the addition of any bonus points earned by the eligible hospital or CAH that could total up to 105 possible points. We believe an eligible hospital's or CAH's actual score for the Medicare Promoting Interoperability Program measures, which includes any bonus points earned, could constitute other relevant data because it would help consumers make informed decisions regarding their health care team, such as knowing whether and to what extent their health care provider is involved in health information exchange or providing patients with electronic access to their health information. We believe that publicly reporting additional Medicare Promoting Interoperability Program data demonstrates our commitment to providing data to patients, consumers, and health care providers, to assist them in their decision-making; promoting enhanced health information exchange processes across eligible hospitals and CAHs; and continually aligning processes and policies with the Hospital IQR Program and the MIPS Promoting Interoperability performance category. For example, for the MIPS Promoting Interoperability performance category, individual measure scores and the total performance score across all measures reported by eligible clinicians are posted on a CMS website available to the public.

Therefore, in alignment with our goals to encourage interoperability and transparency, in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to publicly report certain Medicare Promoting Interoperability Program data submitted by eligible hospitals and CAHs beginning with the EHR reporting period in CY 2023 (87 FR 28592 through 28593). In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28592 through 28593), we used the term ''total score'' within the public reporting proposals and wish to clarify that we were referring to the ''actual score'' that includes bonus points that could add up to 105 possible points. The language in this final rule has been updated to reflect the distinction and clarification. Specifically, as a first step, we proposed to publish on a CMS website available to the public, the actual score of up to 105 points for each eligible hospital and CAH, and the CMS EHR certification ID that represents the CEHRT used by the eligible hospital or CAH, beginning with the scores and CMS EHR certification IDs for the EHR reporting period in CY 2023. We did not propose to publish individual measure scores at this time, but we will continue to evaluate that possibility for future rulemaking. For example, under our proposal, if an eligible hospital scored a total of 75 points for the EHR reporting period in CY 2023, we would publish the score of 75 points, and not the number of points earned for each individual measure within the score.

We stated that if our proposal is finalized, the actual score and CMS EHR certification ID data could be made available to the public as early as the Fall of CY 2024, or as soon as operationally feasible. In addition, as required by section 1886(n)(4)(B) of the Act, we proposed that eligible hospitals and CAHs would have the opportunity to review their data that we would publish, during a 30-day preview period before the data are made public. We proposed to follow our current policy and operational process that eligible hospitals and CAHs are already familiar with for the Hospital IQR Program and use the Hospital Quality Reporting (HQR) system (formerly, the QualityNet Secure Portal) for eligible hospitals and CAHs to access and review their Medicare Promoting Interoperability Program data during a 30-day preview period before publication. We proposed to post the Medicare Promoting Interoperability Program data using the Compare tool hosted by Health and Human Services currently available at *https://www.medicare.gov/care-compare*.

We invited public comments on these proposals. Specifically, we are interested in comments that provide information on how these proposals might affect existing incentives and burdens under the Medicare Promoting Interoperability Program, as well as the benefit and utility of such data being publicly available. We also sought comments on which Medicare Promoting Interoperability Program data points to publish in future years, including specific objective or measure performance rates.

Comment: A few commenters expressed general support for our proposal to publicly report Medicare Promoting Interoperability Program actual scores because they believe it will promote data transparency and help consumers make informed decisions.

Response: We thank commenters for their support of our proposal and agree that it will help promote data transparency and help consumers make informed decisions.

Comment: A few commenters noted their support for allowing a 30-day review and dispute period prior to publicly posting data. A commenter recommended CMS notify eligible hospitals and CAHs prior to the 30-day review, and another commenter suggested that CMS not publish data until any concerns or disputes that arise during the 30-day review are resolved.

Response: We appreciate commenters' feedback regarding CMS notifying eligible hospitals and CAHs prior to the 30-day review period, and the request that CMS address and resolve any disputes prior to publication. As stated previously, we proposed to follow our current policy and operational process for the 30-day review period that eligible hospitals and CAHs are already

familiar with for the Hospital IQR Program. We proposed to use the Hospital Quality Reporting (HQR) system (formerly, the QualityNet Secure Portal) for eligible hospitals and CAHs to access and review their Medicare Promoting Interoperability Program data during a 30-day preview period before publication.

Comment: Many commenters did not support the proposal to publicly report data stating they do not believe the data would be of interest, hold meaning, or be understandable to consumers; thus, it would not help consumers make informed health care decisions. A few commenters cited that given the complexity of the Medicare Promoting Interoperability Program, the actual score may not accurately reflect eligible hospitals' or CAHs' levels of interoperability, such as supporting patient access to health information. A commenter did not support the proposal to publicly report the EHR Certification ID, stating that health IT vendors do not have control over which functionality eligible hospitals or CAHs choose to implement, therefore this information should not be publicly reported.

Response: We appreciate commenters' feedback and concerns regarding whether the Medicare Promoting Interoperability Program data would be of interest, meaningful, or understandable to consumers, especially as a tool used to help make informed decisions about their health care. As we have previously stated, we believe public reporting demonstrates our commitment to transparency and providing data to consumers, and that these data would help consumers make informed decisions regarding their health care team. This would extend to knowing whether, and to what extent, their health care provider is involved in health information exchange or providing patients with electronic access to their health information. We believe these data depict levels of health IT adoption and functionality across eligible hospitals and CAHs. Additionally, we believe it is important to align policies across CMS programs, and this proposal to publicly report Medicare Promoting Interoperability Program data for eligible hospitals and CAHs aligns with the current policy for the MIPS Promoting Interoperability performance category, wherein individual measure scores and the total performance score across all measures reported by eligible clinicians are posted on a CMS website available to the public.

Comment: Several commenters provided recommendations for CMS to consider if the proposal to publicly report Medicare Promoting Interoperability Program data is finalized. These recommendations include providing explanations of what the Medicare Promoting Interoperability Program score indicates, what the EHR Certification ID is, and the process for searching for the information within the CHLP site. This would allow consumers to understand and determine how the actual score is calculated, emphasizing the importance of presenting data in a format that is both valuable and understandable to multiple audiences. A few commenters recommended CMS include the data in the CMS Provider Data Catalog so it is available to researchers and others seeking to understand the current variability and performance within the Medicare Promoting Interoperability Program. A commenter suggested implementing a ''star rating'' program based on national benchmarks to provide more meaningful information to patients and another commenter urged CMS to ensure any publicly reported data will not have unintended impacts on health care providers or the health care system. A few commenters recommended aligning with the Hospital IQR Program's policy for publicly reporting performance data to ensure information is easily understood. A commenter recommended, if CMS finalizes the proposal, to publish points available and points earned along with the yes and no attestations for measures within the Medicare Promoting Interoperability Program.

Response: We appreciate commenters' recommendations to include explanations of what the Medicare Promoting Interoperability score indicates, as well as recommendations for the specific data points to publish in the future. We also appreciate commenters' recommendations to align with the Hospital IQR Program's policy for publicly reporting. As we have previously stated, we proposed to publicly report these data to align with the Hospital IQR Program and the MIPS Promoting Interoperability performance category public reporting policies. We also appreciate the recommendation to include a key for consumers alongside the publicly reported data allowing consumers to better understand the data. We may consider this feedback in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to publicly report certain Medicare Promoting Interoperability program data submitted by eligible hospitals and CAHs beginning with the EHR reporting period in CY 2023. We are finalizing our proposal to publish, on a CMS website available to the public, the actual score of up to 105 points for each eligible hospital and CAH, and the CMS EHR certification ID that represents the CEHRT used by the eligible hospital or CAH, beginning with the EHR reporting period in CY 2023. Additionally, and as required by section 1886(n)(4)(B) of the Act, we are finalizing our proposal that eligible hospitals and CAHs would have the opportunity to review their data that we would publish, during a 30-day preview period before the data are made public. We finalized our proposal to follow our current policy and operational process that eligible hospitals are already familiar with for the Hospital IQR Program and use the Hospital Quality Reporting (HQR) system (formerly, the QualityNet Secure Portal) for eligible hospitals and CAHs to access and review their Medicare Promoting Interoperability Program data during a 30-day preview period before publication. We are also finalizing our proposal to post the Medicare Promoting Interoperability Program data using the Compare tool hosted by Health and Human Services currently available at: *https://www.medicare.gov/care-compare*.

8. Modifications and Additions to the Regulatory Text

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41668), we finalized the objectives, measures, exclusion criteria, and scoring methodology for eligible hospitals and CAHs attesting under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019 and codified these policies in paragraph (e) under 42 CFR 495.24. We have updated the regulatory text to reflect policy changes in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42616), the FY 2021 IPPS/LTCH PPS final rule (85 FR 59026), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45522).

We note that historically, the objectives, measures, exclusion criteria, and associated scoring methodology for the Medicare Promoting Interoperability Program have been included in both the preamble and associated regulatory text under 42 CFR part 495 (see, for example, the Medicare and Medicaid EHR Incentive Programs Stage 1 final rule (75 FR 44314)). We also note that many CMS quality reporting and performance-based programs, including, but not limited to, the Hospital VBP Program, Hospital IQR Program, the End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Quality Payment Program/MIPS, do not

include the text of the measures (also referred to as the measure specifications) adopted for those programs in the Code of Federal Regulations. Instead, the measure specifications generally are included in the rulemaking preamble or maintained by measure stewards outside of CMS and referenced in the preamble. For example, the specifications for the objectives and measures for the Promoting Interoperability performance category of MIPS are not included in the regulatory text for the program under 42 CFR part 414 and instead appear in the preamble only (for example, see CY 2022 PFS final rule (86 FR 65466 through 65485)).

We believe that aligning with the approach taken by other CMS programs to include measures only in the preamble would simplify the Medicare Promoting Interoperability Program and minimize confusion by ensuring consistency across similar CMS programs. We also believe taking this approach for the Medicare Promoting Interoperability Program would reduce burden on regulated parties, CMS, and the general public both during and outside of the rulemaking process. Ensuring the objectives and measures are described consistently in the preamble and regulation text can involve significant effort in terms of time and resources, and inconsistency has the potential to create confusion for regulated parties and the general public. For these reasons, we proposed to remove the text of the objectives and measures for the Medicare Promoting Interoperability Program from paragraph (e) under 42 CFR 495.24 beginning in CY 2023 (87 FR 28593 through 28594). We noted that this proposal does not include any changes in policy for the Medicare Promoting Interoperability Program, including changes to the objectives and measures (87 FR 285593). We referred readers to the proposed changes in policies related to objectives and measures in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28579 through 28581). We also emphasized that this proposal does not change our view that the objectives and measures are rules intended to bind regulated parties, nor does it change our intention to enforce the objectives and measures. Specifically, we proposed to modify the introductory paragraph to 42 CFR 495.24 and paragraph (e) and to establish a new paragraph (f), under 42 CFR 495.24 as described in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28593 through 28594). In the event that our proposals are not finalized, we proposed that we would update the regulatory text to reflect those policy changes to the objectives and measures in this final rule.

TABLE IX.H.-06: PROPOSED MODIFICATIONS AND ADDITIONS TO THE REGULATORY TEXT UNDER 42 CFR 495.24

Objectives and Measures	Regulatory Text Impacted	Proposed Regulatory Text Modifications and Additions
§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years	§ 495.24 –(Introductory text)	Modification--To remove "for 2019 and subsequent years" and add "for 2019 through 2022. Addition—Add the following sentence to the end of the introductory paragraph: "The criteria specified in paragraph (f) of this section are applicable for eligible hospitals and CAHs attesting to CMS for 2023 and subsequent years."
Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2019 and subsequent years	§ 495.24(e) – (Heading)	Modification--In paragraph heading: delete "for 2019 and subsequent years" and to add "for 2019 through 2022."
General rule	§ 495.24(e)(1)(i)(C)	Modification--Delete "In 2022 and subsequent years, earn" and to add "In 2022, earn" at § 495.24(e)(1)(i)(C).
Protect Patient Health Information	§ 495.24(e)(4)(ii)	Modification--Remove "In 2022 and subsequent years" and to add "In 2022" at § 495.24(e)(4)(ii).
Electronic Prescribing	§ 495.24(e)(5)(ii)(B)*	Modification--Delete "In 2020 and subsequent years" and to add "In 2020 through 2022" at § 495.24(e)(5)(ii)(B).
Electronic Prescribing	§ 495.24(e)(5)(iii)(A)*	Modification--Delete "in CY 2019 and subsequent years" and to add "in CY 2019 through CY 2022".
Electronic Prescribing	§ 495.24(e)(5)(v)*	Modification--Delete "Beginning with the EHR reporting period in CY 2019" and to add "For the EHR reporting periods in CY 2019 through CY 2022".
Provider to Patient Exchange	§ 495.24(e)(7)(ii)	Modification--Delete "beginning in CY 2019" and to add "for CY 2019 through CY 2022." at § 495.24(e)(7)(ii).
Public Health and Clinical Data Exchange	§ 495.24(e)(8)	Modification--Delete "For CY 2022 and subsequent years" and to add "For CY 2022" at § 495.24(e)(8)(ii) introductory text; (e)(8)(ii)(A); (e)(8)(iii) introductory text; (e)(8)(iii)(A)(*2*); (e)(8)(iii)(D)(*2*); and (e)(8)(iii)(E)(*2*).
Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2023 and subsequent years	§ 495.24(f) –	Addition-- Adds new paragraph (f) that would set forth the Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2023 and subsequent years. (See § 495.24(f) of the regulations text for the proposed requirements.)

* The FY 2023 IPPS/LTCH PPS proposed rule inadvertently included an incorrect numerical reference that has been corrected in this table.

We invited public comment on our proposed modifications and additions to the regulatory text at 42 CFR 495.24 beginning in CY 2023.

We received no comments on this proposal, and for the reasons stated in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28593 through 28594), we are finalizing our proposal without modification.

9. Overview of Objectives and Measures for the Medicare Promoting Interoperability Program for the EHR Reporting Period in CY 2023

For ease of reference, Table [IX.H.-07.] lists the objectives and measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2023 as revised to reflect the final policies established in this final rule. Due to our modifications to the regulatory text at 42 CFR 495.24(e) (described in section [IX.H.8.] of the preamble of this final rule), we are adding a column to Table [IX.H.-07.] indicating whether the measures that count unique patients or actions may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT or must be calculated by reviewing all patient records, which is intended to reflect the

policy codified at 42 CFR 495.24(e)(3). Table [IX.H.-08.] lists the 2015 Edition certification criteria required to meet the objectives and measures.

TABLE IX.H.-07.: SUMMARY OF OBJECTIVES AND MEASURES FOR THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM FOR THE EHR REPORTING PERIOD IN CY 2023

Objective	Measure	Numerator	Denominator	Exclusion	Calculation Considerations Related to Counting Unique Patients or Actions
Electronic Prescribing	e-Prescribing:* At least one hospital discharge medication order for permissible prescriptions (for new and changed prescriptions) is queried for a drug formulary and transmitted electronically using certified electronic health record technology (CEHRT).	The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically.	The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.	Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Electronic Prescribing	Query of Prescription Drug Monitoring Program (PDMP):* For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period. Any eligible hospital or CAH that could not report on this measure in accordance with applicable law.	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Health Information Exchange	Support Electronic Referral Loops by	Number of transitions of care and referrals in the denominator	Number of transitions of care and referrals during the EHR reporting	N/A	Measure may be calculated by reviewing only

	Sending Health Information: For at least one transition of care or referral, the eligible hospital or CAII that transitions or refers its patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) Electronically exchanges the summary of care record.	where a summary of care record was created using CEHRT and exchanged electronically.	period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transitioning or referring provider.		actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list using CEHRT.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication Allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using certified electronic health record technology (CEHRT) for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.	N/A	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Health Information Exchange	HIE Bi-Directional Exchange The eligible hospital or CAH must attest to the following: (*1*) Participating in an HIE in order to	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A (measure is Y/N)	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the

	enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (*2*) Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. (*3*) Using the functions of CEHRT to support bi-directional exchange with an HIE.				record to be saved and not rejected due to incomplete data.
Health Information Exchange	Enabling Exchange under TEFCA* The eligible hospital or CAH must attest to the following: (1) Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the Federal Register and on ONC's website)	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A

	in good standing (that is not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (2) Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.				
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21or 23): (1) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) the eligible hospital or CAH ensures the patient's health information is available for the	The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the eligible hospitals or CAH's CEHRT.	The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.	N/A	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

	patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interface (API) in the eligible hospital or CAH's CEHRT.				
Public Health and Clinical Data Exchange	Immunization Registry Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the eligible hospital or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or IIS during the EHR reporting period; (2) Operates in a jurisdiction for which no immunization registry or IIS is capable of accepting the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no immunization registry or IIS has declared readiness to receive immunization data as of six months prior to the start of the EHR reporting period.	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit syndromic surveillance data	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency department; (2) Operates in a	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not

	from an emergency department (POS 23).			jurisdiction for which no PHA is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of six months prior to the start of the EHR reporting period.	rejected due to incomplete data.
Public Health and Clinical Data Exchange	Electronic Case Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit case reporting of reportable conditions.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHS has declared readiness to receive electronic case reporting data as of six months prior to the start of the EHR reporting period.	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Public Health and Clinical Data Exchange	Electronic Reportable	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded	Measure may be calculated by reviewing only actions for patients

	Laboratory (ELR) Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit ELR results.			from the case reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in their jurisdiction during (EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of accepting the specific ELR standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive ELR results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.	whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Public Health and Clinical Data Exchange	Public Health Registry Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit data to public health registries.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: The eligible hospital or CAH is in active engagement to submit data to a clinical data registry (CDR).	N/A (measure is Y/N)	N/A (measure is Y/N)	None	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Protect Patient Health Information	Security Risk Analysis Conduct or review a security risk analysis in accordance with	N/A (measure is Y/N)	N/A (measure is Y/N)	None	Measure may be calculated by reviewing only actions for patients whose records are

	the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.				maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Protect Patient Health Information	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) Conduct an annual self- assessment using all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.

TABLE IX.H.-08: MEDICARE PROMOTING INTEROPERABILITY PROGRAM OBJECTIVES AND MEASURES AND 2015 EDITION CERTIFICATION CRITERIA

Objective	Measure	2015 Edition (CY 2023 EHR Reporting Period)*
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Health Information Exchange (alternative)	Enabling Exchange Under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(8) Application access — data category request
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance

	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Electronic reportable laboratory result reporting	§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
	AUR Surveillance Reporting (for 2024)	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
Electronic Clinical Quality Measures (eCQMs)	eCQMs for eligible hospitals and CAHs	§ 170.315(c)(1)
		§ 170.315(c)(2)
		§ 170.315(c)(3)(i) and (ii)
		§ 170.315(c)(4) (optional)
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion.
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	No 2015 health IT certification criteria at this time.

*The ONC Cures Act final rule made changes to the existing 2015 Edition Health IT Certification Criteria by introducing new criteria, and revising and removing existing criteria (85 FR 25667 through 25668). These changes are required for the CY2023 EHR reporting period.

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10. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. Changes to Clinical Quality Measures in Alignment With the Hospital IQR Program

(1) Background

Under sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures selected by CMS using CEHRT (also referred to as electronic clinical quality measures, or eCQMs), as part of being a meaningful EHR user under the Medicare Promoting Interoperability Program.

Tables IX.H.-09. through IX.H.-11. summarize the previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare Promoting Interoperability Program for the CY 2022 reporting period, the CY 2023 reporting period, and the CY 2024 reporting period and subsequent years (86 FR 45496 through 45497). The tables include the Safe Use of Opioids—Concurrent Prescribing measure (NQF #3316e), which we finalized as mandatory for reporting beginning with the CY 2022 reporting period (84 FR 42598 through 42600).

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TABLE IX.H.-09: PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2022 REPORTING PERIOD

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

TABLE IX.H.-10.: PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2023 REPORTING PERIOD

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
HH-02	Hospital Harm–-Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm-Severe Hypoglycemia Measure	3503e
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

TABLE IX.H.11: PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2024 REPORTING PERIOD AND SUBSEQUENT YEARS

Short Name	Measure Name	NQF No.
HH-02	Hospital Harm-Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm-Severe Hypoglycemia Measure	3503e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

(2) eCQM Adoptions

As we have stated previously in rulemaking (82 FR 38479), we intend to continue to align the eCQM reporting requirements for the Medicare Promoting Interoperability Program with similar requirements under the Hospital IQR Program to the extent feasible. Section 1886(n)(3)(B)(i)(I) of the Act provides in part that in selecting clinical quality measures for the Medicare Promoting Interoperability Program, the Secretary shall provide preference to such measures that have been selected for purposes of the Hospital IQR Program (section 1886(b)(3)(B)(viii) of the Act). In addition, section 1886(n)(3)(B)(iii) of the Act provides that in selecting clinical quality measures for the Medicare Promoting Interoperability Program, and in establishing the form and manner for reporting, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under the Hospital IQR Program. To minimize redundant or duplicative reporting, while maintaining a set of meaningful clinical quality measures that continue to incentivize improvement in the quality of care provided to patients, we proposed to adopt four new eCQMs for the Medicare Promoting Interoperability Program in alignment with the Hospital IQR Program, as further discussed in this section of the final rule.

In alignment with proposals for the Hospital IQR Program eCQM measure set, we proposed two new eCQMs that address factors contributing to maternal mortality and morbidity, beginning with the CY 2023 reporting period. Specifically, we proposed to add the following eCQMs in the Medicare Promoting Interoperability Program eCQM measure set beginning with the CY 2023 reporting period: (1) Severe Obstetric Complications eCQM (NQF NA); and (2) Cesarean Birth eCQM (NQF NA) (87 FR 28609). We also proposed to require mandatory reporting of the Severe Obstetric Complications eCQM and Cesarean Birth eCQM for the CY 2024 reporting period and for subsequent years. We refer readers to the discussion of the same proposals for the Hospital IQR Program in sections IX.E.5.d. and IX.E.5.c. of the preamble of this final rule for more information about these proposed measures.

We invited public comments on these proposed measures for the Medicare Promoting Interoperability Program.

Comment: Several commenters support our proposal to adopt the Severe Obstetric Complications eCQM in alignment with the Hospital IQR Program. A few commenters requested a delay in mandatory reporting until the CY 2025 reporting period, or until the measure receives NQF endorsement. A commenter recommended optional reporting if NQF endorsement is received.

Response: We thank commenters for their support. We disagree with commenters who have suggested delaying reporting until the CY 2025 reporting period. Addressing factors contributing to maternal mortality and morbidity is one of our priorities. The Severe Obstetric Complications eCQM has been developed to focus on the high maternal morbidity and mortality rates in the U.S. which we believe will present important opportunities for large-scale quality measurement and improvement activities.[1135] The Severe Obstetric Complications eCQM was also reviewed by the NQF Measure Applications Workgroup (MAP) Hospital Workgroup on December 15, 2021 and received conditional support pending NQF endorsement.[1136] The MAP Coordinating Committee, which provides direction to the MAP workgroups, reviewed the Severe Obstetric Complications eCQM on January 19, 2022, and voted to uphold the MAP Hospital Workgroup recommendation for conditional support pending NQF endorsement.[1137] We acknowledge commenters' recommendations that we seek NQF endorsement for the measure; the Severe Obstetric Complication eCQM was submitted to NQF in January 2022 and is currently under review (87 FR 28512).

Comment: Several commenters supported the proposal to add the Cesarean Birth eCQM and mandatory reporting of this measure. A commenter supported the adoption of the measure for self-selection rather than mandatory reporting. A commenter supported adoption and mandatory reporting and recommended identification of community partners such as HIEs for data capture and sharing. A few commenters supported the measure adoption and requested an adoption delay until NQF endorsement is received. A commenter supported the proposal and requested clarifications on the reporting requirements for non-birthing eligible hospitals and CAHs.

Response: We thank commenters for their support of the Cesarean Birth eCQM. We believe adopting the Cesarean Birth eCQM addresses a priority area.[1138] We also believe adopting measures like the Cesarean Birth eCQM presents unique opportunities for large-scale quality measurement and activities that can improve the short- and long-term health outcomes for mothers and children (87 FR 28508). As a result, we believe that the timeline should not be further delayed as the urgency of the quality issues necessitates making the measure mandatory for data collection from all participating hospitals, not just those hospitals that self-select to report on the measure. We also believe the voluntary reporting in the CY 2023 reporting period before mandatory reporting beginning with the CY 2024 reporting period balances the urgency of the measure with the need for EHR vendors and hospitals to incorporate, adopt, and implement this measure. We acknowledge the comment regarding community partners such as HIEs for data capture and sharing and refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. Under these requirements, hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format, (2) may use third parties to submit QRDA I files on their behalf, and (3) may either use abstraction or pull the data from noncertified sources in order to then input these data into CEHRT for capture and reporting QRDA I. However, we do not currently have a policy to publicly identify any such third parties. We acknowledge commenters' recommendations that we seek NQF endorsement for the measure. As stated in the FY 2023 IPPS/LTCH PPS proposed rule, the NQF has endorsed the chart-abstracted version of this measure and the measure steward has submitted the eCQM to NQF for

[1135] National Quality Forum. (2022). Measure Applications Partnership (MAP) 2021–2022 Final Recommendations. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96698.*

[1136] National Quality Forum. (2022). Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care: Final Report. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-.*

[1137] National Quality Forum. (2022). Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care: Final Report. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[1138] Department of Health and Human Services. (2020). Healthy Women, Healthy Pregnancies, Health Futures: Action Plan to Improve Maternal Health in America. Available at: *https://aspe.hhs.gov/sites/default/files/private/aspe-files/264076/healthy-women-healthy-pregnancies-healthy-future-action-plan_0.pdf.*

consideration of endorsement (87 FR 28509). We also note that the measure steward submitted this measure for endorsement in the Spring of 2022. Non-birthing eligible hospitals and CAHs that do not perform deliveries would submit a zero denominator declaration that allows a hospital to meet the reporting requirements for an eCQM if the hospital does not have patients that meet the denominator criteria of the measure. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57153) where we stated that utilization of the zero denominator declaration and case threshold exemptions are considered as part of the criteria for successful submissions when reporting eCQMs (81 FR 57170). Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387). We also refer readers to the FY 2018 IPPS/LTCH PPS final rule (81 FR 57255 through 57257) where we stated the finalized successful submission requirements in the Hospital IQR Program align with the CQM electronic reporting requirements of the Medicare Promoting Interoperability Program for eligible hospitals and CAHs. For additional information about the requirements for successful submission of eCQMs, we refer readers to our QualityNet website (*https://qualitynet.cms.gov/inpatient/measures/ecqm/participation*).

Comment: Several commenters did not support the proposal to adopt the Severe Obstetric Complications eCQM in the measure set, expressing concerns about feasibility and reliability and the lack of NQF endorsement, the proposal for mandatory reporting, vendors' ability to support the measure, and the measure's achievement of its stated goal. A few commenters offered recommendations about the proposal including securing NQF endorsement before requiring reporting in the Medicare Promoting Interoperability Program. A commenter encouraged CMS to collaborate with eligible hospitals and CAHs, and connect the measurement to community-involved initiatives to reduce complications.

Response: We appreciate commenters' concerns and believe that this measure serves as a key activity in measuring and promoting quality improvement in maternity care by incentivizing eligible hospitals and CAHs to track and report severe obstetric complications and to publicly report the measure data for transparency. As with the Cesarean Birth eCQM, due to the priority on improving maternity care particularly to reduce morbidity and mortality during inpatient births, we believe the timeline for reporting the Severe Obstetric Complications eCQM is appropriate and should not be further delayed. We acknowledge commenters' recommendations that we seek NQF endorsement for the measure; the Severe Obstetric Complication eCQM was submitted to NQF in January 2022 and is currently under review (87 FR 28512). Testing established the feasibility of the measure, first in 25 hospitals across eight healthcare sites and then in additional hospitals unaffiliated with the first 25. The data elements were feasible to collect across three different electronic health record systems.[1139] All numerator indicators and 30 of 34 risk factors use easily mapped ICD–10 codes. The two laboratory and two vital sign risk factors were chosen in part because of their availability and high rates of extractability from the medical record. Using NQF's eCQM Feasibility Scorecard template,[1140] the measure developer calculated results which indicated high feasibility of data elements defining the measure specifications (98 percent), clinical and documentation workflows compared to measure intent (99 percent), data element availability (95 percent) and accuracy (98 percent), and use of data standards (96 percent).

Comment: Several commenters did not support the proposal to adopt the Cesarean Birth eCQM due to concerns about feasibility and validity, the adequacy of the adoption timeline for hospitals and vendors, and the measure as an indicator of quality performance. A few commenters recommended that CMS consider further refining the measure exclusions.

Response: We thank commenters for sharing their concerns and their input on the timeline of adoption, and implementation of the Cesarean Birth eCQM. With regard to feasibility and validity, the measure steward conducted additional measure testing in 2021. The reliability and validity testing found the measure to have an overall data element agreement rate of 92.2 percent and we therefore believe the measure to be reliable and valid for use. As we noted in the preamble of the FY 2023 IPPS/LTCH PPS proposed rule, we are proposing eCQMs that address factors contributing to maternal mortality and morbidity (87 FR 28609) in alignment with proposals for the Hospital IQR Program that address maternal health outcomes. We believe the proposed timeline of inclusion of this eCQM into the Medicare Promoting Interoperability Program measure set beginning with the CY 2023 EHR reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period and for subsequent years, provides sufficient time for EHR vendors and hospitals to incorporate, adopt, and implement the measure. We believe one year of voluntary reporting is sufficient because as noted in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28509), in 2020, the measure steward introduced the Cesarean Birth eCQM as one of the available eCQMs hospitals can choose for data submission to meet The Joint Commission's ORYX® requirements.

We agree that continued monitoring of the measure is important. We believe collecting data and reporting results will provide a critical baseline and we will monitor the data and any unintended consequences of the measure. While we agree that there are many ways to track data related to the C-section rate in the United States, and ultimately reduce excess non-medically indicated C-sections, the standards and comprehensiveness of initiatives can vary widely and we do not believe broadening exclusion criteria or risk adjustment is necessary at this time. As we noted in the FY 2023 IPPS/LTCH PPS proposed rule, when developing the measure, the exclusion criteria were chosen to ensure that the focus population would be women with NTSV pregnancies (86 FR 28510). Barring the presence of other co-morbidities, such women often have a lower risk of maternal morbidity and mortality at the time of delivery than their counterparts who have undergone a previous C-section (87 FR 28510). As a result of the existing exclusion criteria, the population denominator allows the measure to focus on a more homogeneous group where the greatest improvement opportunity exists. As evidenced by variation in rates of NTSV C-sections, clinical practice patterns in particular may affect this rate (87 FR 28510). Lowering the C-section rate in NTSV pregnancies is important because C-sections may carry a higher risk of subsequent miscarriage, placental abnormalities, and repeat C-section (87 FR 28510). The rates of ruptured uteri, unplanned hysterectomies, and ICU admission are higher among women who deliver via C-section for the first time than those who deliver vaginally

[1139] Centers for Medicare & Medicaid Services. (2018). eCQM Feasibility: How Stakeholders Inform Measure Development. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/eCQM-Feasibility.pdf*.

[1140] National Quality Forum. (2022). NQF eCQM Feasibility Scorecard. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89036*.

for the first time across all races and ethnicities. However, non-Hispanic Black women who deliver via C-section for the first time had the highest rates of uterine rupture and ICU admission compared with all other races.[1141] Including a comprehensive set of maternal medical exclusions would add data collection burdens without commensurate benefit. After consideration of the public comments we received, we are finalizing our proposal to add the following eCQMs in the Medicare Promoting Interoperability Program eCQM measure set beginning with the CY 2023 reporting period: (1) Severe Obstetric Complications eCQM (NQF NA); and (2) Cesarean Birth eCQM (NQF NA), and we are finalizing our proposal to require mandatory reporting of the Severe Obstetric Complications eCQM and the Cesarean Birth eCQM for the CY 2024 reporting period and for subsequent years. We refer readers to the discussion of the same proposals for the Hospital IQR Program in sections IX.E.5.d. and IX.E.5.c. of the preamble of this final rule for more information about these finalized policies.

TABLE IX.H.-12.: ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2023 REPORTING PERIOD

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e
ePC-07/SMM**	Severe Obstetric Complications	NA
ePC-02**	Cesarean Birth	NA

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

** eCQM available for reporting in the CY 2023 reporting period.

We also proposed, in alignment with the proposals for the Hospital IQR Program eCQM measure set, to adopt two new eCQMs which eligible hospitals and CAHs can self-select to report on for the CY 2024 reporting period and subsequent years. These eCQMs focus on opioid-related adverse events during an admission to an acute care hospital, and malnutrition. Specifically, we proposed to add the following two additional eCQMs to the Medicare Promoting Interoperability Program eCQM measure set on which hospitals can self-select to report beginning with the CY 2024 reporting period: Hospital Harm-Opioid-Related Adverse Event eCQM (NQF #3501e) and Global Malnutrition Composite Score eCQM (NQF #3592e). Table IX.H.-13 summarizes the finalized eCQMs in the Medicare Promoting Interoperability Program for the CY 2024 reporting period and subsequent years. We refer readers to the discussion of the same proposals for the Hospital IQR Program in sections IX.E.5.e. and IX.E.5.f. of the preamble of this final rule for more information about these measures and our policy reasons for proposing them.

We invited public comments on these proposed measures for the Medicare Promoting Interoperability Program.

Comment: Many commenters expressed support for our proposal to adopt the Hospital Harm—Opioid Related Adverse Events eCQM (NQF #3501e), stating that its implementation will incentivize opioid adverse event monitoring and reporting, which commenters believe may also address a disproportionate number of inpatient overdose deaths among racial and ethnic minorities. A commenter supported the measure and requested information about performance and what the intended action with the collected data would be.

Response: We thank commenters for their support of the measure. The intent of the measure is to identify if hospitals have particularly high rates of naloxone use, as an indicator of high rates of over-administration of opioids in the inpatient setting, and thereby incentivize improved clinical practices when administering opioids.

Comment: A commenter did not support the proposed adoption of the Hospital Harm—Opioid Related Adverse Events eCQM (NQF #3501e), because the measure focuses on a rare event rather than large population-based approaches and could create unintended consequences and recommended CMS consider or create an alternative measure. A commenter suggested considering a re-specification of the measure for the outpatient setting. A commenter expressed concern that the Hospital Harm—Opioid-Related Adverse Event eCQM does not focus on undertreatment of pain or other symptoms for which opioids may be appropriately prescribed.

[1141] Curtin, S.C., Gregory, K.D., Korst, L.M., Uddin, S.F.G. (2015) Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data from the Birth Certificate, 2013. National Vital Statistics Reports, 64(4). Available at: *https://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_04.pdf.*

Response: We thank commenters for their support of the measure. The intent of the measure is not to reduce clinically appropriate use of naloxone, nor to bring the measure rate to zero, but to identify if hospitals have particularly high rates of naloxone use as an indicator of high rates of over-administration of opioids in the inpatient setting, and thereby incentivize improved clinical practices when administering opioids. We acknowledge that some interested parties have expressed concern regarding the measure's impact given the small number of overall events. However, our overall analysis during testing demonstrated the rate of ORAE ranged from 1.1 to 6.1 per 1,000 qualified inpatient encounters, signaling there is still opportunity for improvement. We also acknowledge that some interested parties have expressed concern that implementation of the measure could result in deterring or delaying clinically appropriate administration of naloxone or under-prescribing of opioids for pain control when clinically necessary. However, we reiterate that naloxone is a life-saving emergent therapy with clear and unambiguous applications in the setting of opioid overdose and we note that it would be unethical to withhold lifesaving medication.

Comment: Many commenters expressed support for our proposal to adopt the Global Malnutrition Composite Score eCQM as there is a gap between performance measures focused on nutrition care and malnutrition. With malnutrition contributing to increased lengths of stay, complications and mortality, commenters believe this measure will benefit patients, families, caregivers and health care providers.

Response: We thank the commenters for their support of our proposal and agree that the adoption of the Global Malnutrition Composite Score eCQM may help address several priority areas identified in the CMS Equity Plan for Medicare. This would allow us to further evaluate the impact of disparities, while integrating equity solutions across CMS programs, and increasing the ability of the healthcare workforce to meet the needs of populations that have been disadvantaged and/or underserved by the healthcare system.

Comment: A commenter did not support our proposal to adopt the Global Malnutrition Composite Score due to the practicality of translating a complex multi-step measure into an eCQM, and have instead requested delaying its adoption for one additional year. A few commenters expressed concern about operationalizing and implementing the measure, its value, and potential duplication with the CMS proposed Health Related Social Needs screening measure.

Response: We appreciate the commenters' concerns about our proposed measure. The Screening for Social Drivers of Health measure, discussed in section IX.E.5.b. of the preamble of this final rule, and the Global Malnutrition Composite Score eCQM both speak to nutrition as a driver of health because it is an important contributor to a healthful population. However, the measures address different but related goals. The Screening for Social Drivers of Health measure focuses on incentivizing the screening and identifying of patients for food insecurity, defined as limited or uncertain access to adequate quality or quantity of food (87 FR 28500). The Global Malnutrition Composite Score eCQM focuses not only on screening for malnutrition risk (of which food insecurity may be a contributing factor) but also the performance of a nutrition assessment and development of a care plan for identified malnourished patients (87 FR 28520). We believe these two measures are equally important and complementary, but not duplicative as they measure different aspects of the care process. We also appreciate the recommendation to delay adoption for one additional year, however we disagree because we have proposed to adopt this as a self-select eCQM. Additionally, we have not yet determined future plans with respect to requiring reporting of this measure. Any proposal to mandate reporting this eCQM would be made through future notice-and-comment rulemaking.

After consideration of the public comments we received, we are finalizing our proposals as proposed. We refer readers to the discussion of the same proposals for the Hospital IQR Program in sections IX.E.5.e. and IX.E.5.f. of the preamble of this final rule for more information about these finalized policies.

TABLE IX.H.-13: ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2024 REPORTING PERIOD AND SUBSEQUENT YEARS

Short Name	Measure Name	NQF No.
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e
ePC-07/SMM***	Severe Obstetric Complications	NA
ePC-02***	Cesarean Birth	NA
HH-ORAE****	Hospital Harm-Opioid Related Adverse Event	3501e
GMCS****	Global Malnutrition Composite Score	3592e

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

*** Reporting the Severe Obstetric Complications eCQM (ePC-07) and Cesarean Birth (ePC-02) is mandatory beginning with the CY 2024 reporting period.

****Hospital Harm-Opioid Related Adverse Event eCQM and Global Malnutrition Composite Score eCQM available for reporting beginning with the CY 2024 reporting period.

b. eCQM Reporting and Submission Requirements for the CY 2024 Reporting Period and Subsequent Years

Consistent with our goal to align the eCQM reporting periods and criteria in the Medicare Promoting Interoperability Program and the Hospital IQR Program, we previously finalized the requirement that eligible hospitals and CAHs reporting eCQMs for the Medicare Promoting Interoperability Program must report four calendar quarters of data from CY 2023 and each subsequent year for: (a) Three self-selected eCQMs from the set of available eCQMs for CY 2023 and each subsequent year, and (b) the Safe Use of Opioids-Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs (85 FR 58975). We did not propose to change the data reporting and submission requirements for the CY 2023 reporting period.

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28610), in alignment with proposals for the Hospital IQR Program, we proposed to modify the eCQM reporting and submission requirements under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs beginning with the CY 2024 reporting period such that hospitals would be required to report four calendar quarters of data for each required eCQM: (1) Three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the proposed Severe Obstetric Complications eCQM; and (4) the proposed Cesarean Birth eCQM, for a total of six eCQMs, beginning with the CY 2024 reporting period and for subsequent years. We noted that the number of calendar quarters of data required and the number of self-selected eCQMs would remain the same, but we proposed to increase the number of eCQMs that all eligible hospitals and CAHs would be required to report from one to three. This proposal was made in conjunction with our proposals discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28609), in which we proposed to adopt the Severe Obstetric Complications eCQM and Cesarean Birth eCQM, respectively. We stated that we believe by 2024, eligible hospitals and CAHs will have had sufficient experience with eCQM reporting to propose an increase in the number of required eCQMs from four to six eCQMs. In addition, we stated that we believe in light of the maternal health crisis as described in sections IX.E.5.d.(1) and IX.E.5.c.(1) of this final rule, and our commitment to reducing unacceptably high maternal morbidity and mortality rates, it is important to collect and utilize quality measure data focused on maternal health to incentive improved quality of care.

As detailed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28610), we proposed that if our proposals to adopt the Severe Obstetric Complications eCQM and the Cesarean Birth eCQM are finalized, these measures would be available for eligible hospitals and CAHs to select as one of their three self-selected eCQMs for the CY 2023 reporting period, and then beginning with the CY 2024 reporting period, all eligible hospitals and CAHs would be required to report these two eCQMs. We referred readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28555) for the reporting and submission requirements associated with the proposal to modify the eCQM reporting requirements for the Hospital IQR Program. We invited public comments on these proposed eCQM reporting requirements.

Comment: A few commenters supported our proposal to modify the reporting and submission requirements for eCQMs such that beginning with the CY 2024 reporting period/FY 2026 payment determination hospitals would be required to submit four calendar quarters of data from three self-selected eCQMs and three required eCQMs.

Response: We thank commenters for their support.

Comment: A commenter supported the proposal to modify eCQM reporting

and submission requirements and requested two years of voluntary reporting for the Severe Obstetric Complications eCQM before mandatory reporting.

Response: We thank the commenter for their support of our proposal but, regarding a delay in mandatory reporting of our two finalized perinatal eCQMs, reiterate that addressing the maternal health crisis, improving maternal health, and closing any gaps that exist as a result of health disparities are among our top goals and mandatory reporting of the Severe Obstetric Complications eCQM beginning with the CY 2024 reporting period advances that goal.

Comment: Many commenters did not support the proposal to modify eCQM reporting and submission requirements due to current eCQM challenges such as the lack of frequent and actionable eCQM performance feedback, difficulties extracting data from production ready eCQM products delivered by developers, insufficient time for vendor design and development and for hospitals to complete testing, validation, staff education before required reporting, and the costly and prolonged process of eCQM health care provider adoption. A few commenters recommended a delayed and phase implementation of modified reporting and submission requirements as clinical quality measure reporting is moving from eCQMs to dQMs.

Response: We appreciate commenters' concerns related to modifications of the eCQM reporting and submission requirements due to eCQM reporting challenges experienced by hospitals. We urge hospitals to continue to work with their vendor to secure timely delivery of their products and we believe our finalized policy will offer opportunities for hospitals that are prepared to voluntarily report the two perinatal eCQMs to do so for the CY 2023 reporting period while providing more than one year for other hospitals to prepare and implement the two perinatal eCQMs for the CY 2024 reporting period.

With respect to the challenges of extracting eCQM data, we believe that our proposal to modify the eCQM reporting and submission requirements advances our goal of increasing the use of EHR data for quality measurement and improvement. We also believe the implementation of the production ready product supports feasible data extraction processes, and we will be considerate of this feedback in future rulemaking.

We understand commenters' concerns related to the effort by hospitals to customize their health IT and to potentially update workflows and train staff following vendor delivery of their product; however, we expect the burden for hospitals to be no greater than that already required to comply with CMS annual updates which includes the eCQM specifications, educational materials, value sets, code systems direct reference codes, and terminology that are posted on the eCQI Resource Center.[1142]

We recognize the process of hospital adoption of eCQMs can be costly and prolonged. We refer readers to section XII.B.9.e. of the preamble of this final rule (information collection requirements) for a detailed discussion of our burden estimates associated with the modification of our eCQM reporting and submission requirements. We believe the long-term benefits associated with reporting a full year of data for six eCQMs will outweigh the burdens and that increasing the number of eCQMs for which hospitals are required to report will produce more comprehensive and reliable quality information for patients and health care providers. We will continue to look across CMS programs to identify areas for further streamlining of reporting requirements. Also, as referenced in section IX.C. of the preamble of this final rule, in the ''Continuing to Advance Digital Quality Measurement and Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs—Request for Information,'' we also believe utilizing standardized data for EHR-based measurement (based on the FHIR standard) and aligning where possible with other interoperability requirements can reduce the data collection burden incurred by health care providers.

For the purpose of reporting quality measures and alleviating the concern about the costly and prolonged process of eCQM adoption. We appreciate the comments and interest in opportunities to reduce reporting burden, and we will continue to take all under consideration as we develop future regulatory proposals.

Comment: A commenter did not support due to the cost, time and limited IT resources barriers faced by small rural hospitals for EHR changes and updates.

Response: We appreciate the commenter's concern regarding the cost, time and IT resources required to in eCQM reporting and submission. We establish program requirements considering all hospitals and CAHs that participate in the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, which involves a wide spectrum of capabilities and resources with respect to eCQM reporting. We acknowledge that advancing quality improvement supported by health IT can present unique challenges for small or rural hospitals. We believe our finalized policy to modify the eCQM reporting and submission requirements will offer opportunities for hospitals that are prepared to voluntarily report the two perinatal eCQMs—Cesarean Birth and Severe Obstetric Complications—to do so for the CY 2023 reporting period, while providing more than one year for other hospitals to prepare and implement the two perinatal eCQMs for mandatory reporting in the CY 2024 reporting period and subsequent years. We recognize the cost and time associated with eCQM adoption and refer readers to section XII.B.9.k. of the preamble of this final rule (information collection requirements) for a discussion of our burden estimates associated with the modification of our eCQM reporting and submission requirements. When considering modifications to program requirements, we have, and may continue to, consider the recommendations from the rural health care providers to ensure eCQMs policies are meaningful to quality improvement for small, rural hospitals.

Comment: A few commenters did not support the proposal to modify eCQM reporting and submission requirements and recommended a phased and incremental timeline for increasing the number of required eCQMs. A commenter recommended financial incentives to support hospitals with changing eCQM requirements.

Response: We thank the commenters and acknowledge the concerns about the pace of change in eCQM reporting and submission policy. However, we believe that hospitals have had several years to report eCQM data. After holding eCQM reporting and submission policies constant for a number of years in order to give hospitals and their vendors additional time to improve eCQM reporting capabilities, we intended to transition to more robust reporting.

Comment: Several commenters offered recommendations such as alignment of eCQM data submissions with the quarterly timeline for submission of Hospital IQR Program's chart-based measure data, an analysis of required measures and a proposal to remove measures less impactful to improved health outcomes, limit eCQMs to self-selection until hospitals gain experience to confirm feasibility and reliability, delay of public reporting

[1142] *https://ecqi.healthit.gov/.*

until one year of data is reported and a proposal for a quarter exception rather than a full year hardship exception for eCQM reporting in future rulemaking. A commenter recommended reconsideration of the proposal.

Response: We thank commenters for their comments. Concerning the eCQM data submission timeline, the data submission deadline for eCQM data under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs continues to be the end two months following the close of the calendar year. We note the submission deadline may be moved to the next business day if it falls on a weekend or Federal holiday. We did not propose any changes to this policy in the FY 2023 IPPS/LTCH proposed rule. We plan to monitor the implementation of the finalized eCQM data reporting and submission requirements and welcome continued feedback from stakeholders through webinars, listservs, and help desk questions.

We utilize principles and frameworks to assess clinical quality measures included in our programs including the CMS National Quality Strategy [1143] and the Meaningful Measures Initiative,[1144] which identifies high-priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes. In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements.[1145] We will continue to utilize this approach.

We believe the Cesarean Birth eCQM and Severe Obstetric Complications eCQM present unique opportunities for large-scale quality measurement and activities that can improve the short- and long-term health outcomes for mothers and children (87 FR 28508) and self-selection of these measures would not advance us toward our short-and long-term goals.

We acknowledge commenters' concern about public reporting and refer readers to the FY2021 IPPS/LTCH PPS final rule (85 FR 58976) for a discussion of our previously finalized public reporting of eCQM data policy. Additionally, we would like to remind readers that the Medicare Promoting Interoperability Program allows hardship exception applications for extreme and uncontrollable circumstances, including vendor issues. Additional information on this process is available at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj_Hardship.* We did not propose any changes to this policy in the FY 2023 IPPS/LTCH PPS proposed rule. We thank commenters for their recommendations. We acknowledge commenters' recommendations, and we may continue to take all comments into account as we develop future regulatory proposals.

Comment: A commenter requested clarification for hospitals without obstetric departments or providing labor and delivery services. A commenter expressed concern that hospitals could be penalized due to hospital or vendor inability to meet reporting and submission requirements.

Response: If a hospital does not have an obstetrics department or has few or no deliveries during a reporting period, the hospital may submit a zero-denominator declaration or a case threshold exemption for an eCQM that is being reported. A QRDA Category I file with patients meeting the initial patient population of the applicable measures, a zero-denominator declaration and/or a case threshold exemption all count toward a successful submission for eCQMs for the Medicare EHR Incentive Program (now called the Promoting Interoperability Program) (82 FR 38482). Hospitals may request a hardship exception if they are unable to fulfill program requirements due to extreme and uncontrollable circumstances, including vendor issues. Additional information on this process is available at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj_Hardship*.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

11. Patient Access to Health Information Measure—Request for Information (RFI)

Patient use of portals to access their health information has been tied to benefits such as improvements in access, quality of care, and health outcomes, and reductions in healthcare expenditures.[1146] In particular, access to health information has been shown to enable the discovery of medical errors, to improve medication adherence, and to promote communication between the patient and health care provider.[1147] However, despite the fact that surveyed patients experiencing shared access to notes with health care providers has been largely positive,[1148] voluntary uptake and use of patient portals has been low, with nearly two-thirds of hospitals having less than 25 percent of patients activate access to the hospital's patient portal in 2017.[1149] Health care provider encouragement (and other facilitating conditions), perceived usefulness, ease of use, control of health information, and enhanced communication are demonstrated as facilitators, while concerns of privacy, security, and lack of awareness have been tied to barriers of use.[1150] [1151]

The Health Information National Trends Survey (HINTS), a large, nationally representative survey operated by the National Cancer Institute (with support from ONC), is conducted routinely and contains key utilization data on consumer access and use of their online medical record through patient portals. The HINTS results showed the rates of individuals being offered and subsequently using their health information through a patient portal, as well as use of mobile health applications (apps) and the role health care providers play in

[1143] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[1144] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[1145] Centers for Medicare & Medicaid Services. (2021). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[1146] Ronda MC, Dijkhorst-Oei LT, Rutten GE. Reasons and barriers for using a patient portal: survey among patients with diabetes mellitus. J Med internet Res. 2014 Nov 25;16(11):e263. doi: 10.2196/jmir.3457. PMID: 25424228; PMCID: PMC4260081.

[1147] Wildenbos GA, Peute L, Jaspers M. Facilitators and Barriers of Electronic Health Record Patient Portal Adoption by Older Adults: A Literature Study. Stud Health Technol Inform. 2017;235:308–312. PMID: 28423804.

[1148] Walker J, Leveille S, Bell S, Chimowitz H, Dong Z, Elmore JG, Fernandez L, Fossa A, Gerard M, Fitzgerald P, Harcourt K, Jackson S, Payne TH, Perez J, Shucard H, Stametz R, DesRoches C, Delbanco T. OpenNotes After 7 Years: Patient Experiences With Ongoing Access to Their Clinicians' Outpatient Visit Notes. J Med internet Res.

[1149] Henry J, Barker W, Kachay L. Office of the National Coordinator for Health Information Technology (ONC) Data Brief No. 45 (April 2019). Electronic Capabilities for Patient Engagement among U.S. Non-Federal Acute Care Hospitals: 2013–2017. Available at: *https://www.healthit.gov/sites/default/files/page/2019–04/AHApatientengagement.pdf.*

[1150] Powell KR. Patient-Perceived Facilitators of and Barriers to Electronic Portal Use: A Systematic Review. Comput Inform Nurs. 2017 Nov;35(11):565–573. doi: 10.1097/CIN.0000000000000377. PMID: 28723832.

[1151] Alaa A. Abd-alrazaq, Bridgette M. Bewick, Tracey Farragher, Peter Gardner, Factors that affect the use of electronic personal health records among patients: A systematic review, International Journal of Medical Informatics, Volume 126, 2019, Pages 164–175, ISSN 1386–5056, *https://doi.org/10.1016/j.ijmedinf.2019.03.014.*

encouraging use.[1152] Results showed that health care providers and staff have a substantial role in influencing patient use of the portal.

In the past for the Medicare Promoting Interoperability Program, we attempted to promote patient access to their health information through measuring the number of patients who actively engaged with the electronic health record through the View, Download, or Transmit (VDT) measure at 42 CFR 495.24(c)(6)(ii)(A). In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41668), we renamed the Patient Electronic Access Objective to the Provider to Patient Exchange Objective and updated the measures within the Provider to Patient Exchange Objective. Specifically, we removed the standalone VDT measure from the Medicare Promoting Interoperability Program in response to interested party feedback, including hospitals and hospital associations detailing the significant challenges they faced in implementing measures that require patient action (83 FR 41665). These challenges included, but were not limited to, patients who have limited knowledge of, proficiency with, or access to information technology; patients declining to access the portals provided by the eligible hospital or CAH to view, download, and transmit their health information via this platform; as well as the lack of availability of user-friendly portals and the immaturity of the health IT infrastructure needed to facilitate useful access and use of their own health information. We also noted that data analysis of the VDT measure showed low percentages of patients taking action to view, download, and transmit their health information (83 FR 41665). Additionally, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41661 through 41663) we changed the name of the Provide Patient Access measure at 42 CFR 495.24(c)(5)(ii)(A) to Provide Patients Electronic Access to Their Health Information at 42 CFR 495.24(e)(7)(ii) and finalized changes to the measure description. These measure changes included a requirement for eligible hospitals or CAHs to provide timely access for viewing, downloading or transmitting their health information for at least one unique patient discharged using any application of the patient's choice (83 FR 41661 through 41663). This change emphasized timely electronic access of patient health information rather than requiring health care providers to be accountable for patient actions.

Through the current Provide Patients Electronic Access to Their Health Information measure in the Provider to Patient Exchange Objective, we are ensuring that patients have access to their health information through any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the CEHRT of the eligible hospital or CAH. Promoting the use of API-enabled applications that provide timely access to updated information whenever the patient needs that information is an integral step in enhancing patient access and use of their health information. These API-enabled applications should be configured using standardized technology and contain the information the patient needs to make informed decisions about their care in a way the patient understands, and that recognizes the community's level of access to devices and internet connectivity. While we removed the VDT measure holding eligible hospitals and CAHs responsible for patient action (83 FR 41665), we still require that the technical capabilities be in place within an eligible hospital's or CAH's CEHRT through the Provide Patients Electronic Access to Their Health Information measure should patients choose to access and use their health information (83 FR 41661 through 41663).

We continue to believe in the importance of taking a patient-centered approach to health information access and moving to a system in which patients have immediate access to their electronic health information and can be assured that their health information will follow them as they move throughout the health care system. Recognizing the concerns and barriers with the previous VDT measure discussed previously, but acknowledging the advancements made within the health IT industry over the past few years, this request for information (RFI) sought a broad array of public comments regarding how to further promote equitable patient access and use of their health information without adding unnecessary burden on the hospital or health care provider. Specifically, we sought public comment on the following questions:

- Moving beyond providing the information and technical capabilities to access their data, are there additional approaches to promote patient access and use of their health information? Are there examples of successful approaches or initiatives that have enhanced patient access and use of their health information?

++ Would allowing patients to add information to their records be useful in promoting patient access and utilization? Are there other incentives that would promote patient access?

++ Are there potential unintended consequences in allowing patients to add information to their records? What could be done to mitigate any potential unintended consequences?

++ Are there certain tools found to be useful in promoting patient access and use of their health information?

- Recent studies have raised concerns about the presence of racial bias and stigmatizing language within EHRs that could lead to unintended consequences if patients were to obtain disparaging notes regarding their medical care.[1153] [1154]

++ What policy, implementation strategies, or other considerations are necessary to address existing racial bias or other biases and prevent use of stigmatizing language?

- Additional analysis of HINTS data provides insights into common barriers to patient portal access and use as well as characteristics that can help predict which individuals are more likely to experience certain barriers (for example, preference for in-person communication with their health care provider is one of the most prevalent barriers experienced more often by older adults and women).[1155]

++ What are the most common barriers to patient access and use of their health information that have been observed? Are there differences by populations or individual characteristics?

- Patients' health information may be found in multiple patient portals. How could CMS or HHS facilitate individuals' ability to access all their health information in one place?

++ If patient portals connected to a network participating in the recently launched TEFCA,[1156] [1157] would this

[1152] Johnson C, Richwine C, Patel V. Office of the National Coordinator for Health Information Technology (ONC) Data Brief, No. 57 (September 2021). Individuals' Access and Use of Patient Portals and Smartphone Health Apps, 2020.

[1153] Sun M, Oliwa T, Peek ME, Tung EL. Negative Patient Descriptors: Documenting Racial Bias in the Electronic Health Record. Health Affairs 41, No. 2 (2022): 203–211. doi:10.1377/hlthaff.2021.01423.

[1154] Himmelstein G, Bates D, Zhou L. Examination of Stigmatizing Language in the Electronic Health Record. JAMA Netw Open. 2022;5(1):e2144967. doi:10.1001/jamanetworkopen.2021.44967.

[1155] Turner K, Clary A, Hong Y, Alishahi Tabriz A, Shea CM. Patient Portal Barriers and Group Differences: Cross-Sectional National Survey Study. J Med internet Res 2020;22(9):e18870.

[1156] The Trusted Exchange Framework (TEF): Principles for Trusted Exchange. ONC January 2022: *https://www.healthit.gov/sites/default/files/page/2022–01/Trusted_Exchange_Framework_0122.pdf.*

[1157] Common Agreement for Nationwide Health Information Interoperability V1. ONC. January

enable more seamless access to individual health information across various patient portals?

• With the advancement of HIT, EHRs and other health-related communication technologies, there are concerns of equity to health outcomes and access with populations who could receive greater benefits from these technologies but are less likely to adopt them.[1158] [1159] What policy, governance and implementation strategies or other considerations are necessary to ensure equal access to patient portals, equitable portal implementation, appropriate design and encouragement of use?

• What challenges do eligible hospitals and CAHs face when addressing patient questions and requests resulting from patient access of patient portals or access of data through use of a mobile app? What can be done to mitigate potential burden?

• For patients who access their health information, how could CMS, HHS, and health care providers help patients manage their health through the use of their personal health information?

• Do you believe the API and app ecosystem is at the point where it would be beneficial to revisit adding a measure of patient access to their health information which assesses health care providers on the degree to which their patients actively access their health information?

* What should be considered when designing a measure of patient access of their health information through portals or apps?

We welcomed input on how we can encourage and enable patient access to and use of their health information to manage and improve their care across the care continuum. We thank the interested parties who submitted comments for our review and consideration.

Comment: Many commenters provided input on additional approaches to promote patient access and use of patient health information. Several commenters supported individuals contributing to their own records as an approach to promote patient access to and engagement with their health information. These commenters offered a number of successful suggestions for individuals to contribute to their records, as well as important considerations regarding potentially duplicative or erroneous information being added, and the need for clinical review of information entered by individuals before inclusion in the medical record. A commenter recommended CMS work with ONC to develop certification criteria and technical capabilities to amend or update their records. Several commenters recommended including beneficial capabilities within the patient portal to promote patient access, such as appointment scheduling, prescription refills, immediate release of lab results, push notifications to patients, and secure physician messaging. Many commenters provided support for TEFCA implementation and the use of HIEs as an approach to promote a standard nationwide method of collecting patient health data and consolidating into one view for seamless patient access. Commenters stated that TEFCA has a lot of potential to improve patient access to health information, but CMS should monitor the progress of TEFCA implementation.

Many commenters provided input on potential unintended consequences and concerns around increasing patient access to their health information related to racial bias and stigmatizing language. A few commenters stated the importance of developing educational materials for health care providers to reduce stigmatizing language, including providing guidance on the information blocking regulations so health care providers are aware of requirements for patient access to clinical notes, and provide patient-facing resources to address questions when reviewing records. A few commenters stated the importance of accurate translation of health information from other languages and how technology can provide reliable real-time translation of information contained in a portal. A commenter recommended implementing a policy to permit patients to complete sexual orientation, and gender identity fields within the patient portal.

Many commenters provided input on the potential barriers to patient access including those associated with individuals having limited access to technology or insufficient understanding of how to use health technology who encounter difficulties navigating portals. Several commenters stated that racial and ethnic minority groups, socioeconomically disadvantaged, rural, elderly, and people who are at risk of poor health outcomes lack physical tools including computers, email addresses, smartphones, and inconsistent internet access. Commenters discussed the absence of technical assistance to help patients access information as well as the lack of understanding of their rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, including the right to access an electronic copy when their health information is stored electronically. A commenter stated the success of publishing health care provider compliance rates with patient access requirements under HIPAA and recommended similar approaches to help improve patient access. A few commenters discussed the complications and potential barriers regarding proxy access to patient portals and patient applications. Additionally, commenters stated the lack of a unique patient identifier or identity proofing and authentication creates a barrier to access health information.

Many commenters provided input on challenges and burdens faced by hospitals including cumbersome and decentralized processes for requesting records as well as the manual workflows for health information professionals fulfilling requests. Commenters recommended CMS continue to monitor challenges related to patient access of data and solicit feedback from interested parties, particularly health information professionals who field patient questions and concerns related to the access of data.

Many commenters provided input and recommendations on policy, governance, and implementation considerations for promoting patient access and the role of CMS and HHS. Commenters recommended continued collaboration with OCR and ONC to develop guidance regarding HIPAA requirements, particularly in the context of health information exchanges and networks, as well as guidance regarding the lack of HIPAA protections when data moves to third-party applications. Commenters recommended CMS remain actively engaged in the work of standards development organizations to determine the best avenue for regulatory alignment. Commenters also recommended CMS work with ONC to improve patient matching and identification to promote longitudinal records, and further advance and ensure adoption of standards. Many commenters recommended providing funding for equipment and studying the optimal use of digital technology including wearable devices. A few

2022: *https://www.healthit.gov/sites/default/files/page/2022–01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf*.

[1158] Sarkar U, Karter AJ, Liu JY, et al. The literacy divide: health literacy and the use of an internet-based patient portal in an integrated health system—results from the diabetes study of Northern California (DISTANCE). J Health Commun 2010; 15 (Suppl 2): 183–96.

[1159] Ackerman SL, Sarkar U, Tieu L, et al. Meaningful use in the safety net: a rapid ethnography of patient portal implementation at five community health centers in California. J Am Med Inform Assoc 2017; 24 (5): 903–12.

commenters recommended CMS use their authority and exercise enforcement to ensure health plans subject to CMS oversight facilitate patient access and implement APIs.

Many commenters provided input on the prospect of adding a measure of patient access. A few commenters supported adding a measure for patient access to their health information but several commenters did not support adding a new measure of patient access stating many reasons including lack of control, unnecessary burden, and existing patient access barriers.

Response: We appreciate the comments and suggestions we have received. While we will not be responding to specific comments submitted in response to this RFI, we believe that this input is valuable in our efforts to continue to promote patient access to their health information. We may consider these suggestions in future rulemaking.

X. Changes for Hospitals and Other Providers

A. Codification of the Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans

1. Background

Currently, certain costs incurred on behalf of Deferred Compensation Plans may be allowable costs under Medicare to the extent such costs are related to the reasonable and necessary cost of providing patient care and represent costs actually incurred. Reasonable cost reimbursement is addressed in section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) of the Act defines ''reasonable cost,'' in part, as the cost actually incurred, excluding costs found to be unnecessary in the efficient delivery of needed health services. Section 1861(v)(1)(A) of the Act does not specifically address the determination of reasonable costs, but authorizes the Secretary to promulgate regulations and principles to be applied in determining reasonable costs.

We have issued regulations implementing this provision of the Act, including 42 CFR 413.9(a), which provides that the payments ''must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries.'' In addition, § 413.9(c)(2) states that ''[t]he provision in Medicare for payment of reasonable cost of services is intended to meet the actual costs.'' Further, § 413.9(c)(3) provides that ''[r]easonable cost includes all necessary and proper expenses incurred in furnishing services . . . .'' Therefore, in accordance with the statute, the regulations include two principles that help guide the determination of which expenses may be considered allowable reasonable costs that can be paid under Medicare; that is, such costs must be ''related'' to the care of Medicare beneficiaries, and such costs must actually be ''incurred.''

Consistent with these provisions, we have issued instructions in sections 2140 through 2142 of the Medicare Provider Reimbursement Manual, Part I (PRM–I) for determining and reporting the policies that govern how providers of services are to determine and report the allowable costs of Deferred Compensation Plans. Section 2140.1 of PRM–I defines Deferred Compensation as ''remuneration currently earned by an employee but which is not received until a subsequent period, usually after retirement. Accordingly, a Deferred Compensation Plan defers the receipt of income beyond the year in which it is earned.'' The policies for Deferred Compensation plans that we have established in sections 2140 through 2142 of PRM–I vary depending on whether a plan is funded using an allowable funding mechanism or unfunded, and whether a plan is a Defined Contribution plan or a Defined Benefit plan. The term funded essentially means that funds are set aside to protect payment of future benefits for plan participants, and not simply paid out of current revenues, as is the case with unfunded plans. Allowable Non-Qualified Deferred Compensation Plan costs that are considered unfunded are based on reasonable benefits that providers of services paid to participating employees.

Allowable Defined Contribution plan costs are based on reasonable contributions made by providers of services to Defined Contribution accounts. Prior to August 2011, allowable funded Defined Benefit plan costs were based on Employee Retirement Income Security Act of 1974 (ERISA) components of accrued pension costs (for example, Normal Cost, Actuarial Accrued Liability, Actuarial Value of Assets) if the resulting computation of costs was funded into an approved account. In August 2011, the FY 2012 IPPS/LTCH PPS final rule (76 FR 51693 through 51697), established regulations for reporting costs of Qualified Defined Benefit plans for Medicare cost-finding purposes. Specifically, for cost reporting periods beginning on or after October 1, 2011, a provider of services cost equals the cash basis contribution deposits plus any carry forward contributions, subject to a limitation (§ 413.100(c)(2)(vii)(D)(*1*)). Providers of services with current contributions and carry forward contributions that exceed the limit may request approval of excess contributions, which are reviewed by the contractor on a case-by-case basis (§ 413.100(c)(2)(vii)(D)(*3*)).

At the time the FY 2012 IPPS/LTCH final rule was issued, the regulations at §§ 413.24 and 413.100 specified that pension costs of Qualified Defined Benefit plans were reported on an accrual basis of accounting method. To conform this accrual requirement in the regulations with the cash-basis methodology for reporting pension costs finalized in the FY 2012 IPPS/LTCH PPS final rule, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53448), we amended the general cost reporting rules under §§ 413.24(a)(2) and 413.100(c)(2)(vii)(D) to note the exception for recognizing actual contributions funded during the cost reporting period on a cash basis.

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28612 through 28618), we proposed to codify and clarify additional policies relating to Deferred Compensation in a new section in part 413, subpart F. We did not propose to change our current policies for allowable Deferred Compensation costs associated with Qualified and Non-Qualified Deferred Compensation Plans (the plans) that are included in Medicare cost reports. Nor did we propose to change the way in which Deferred Compensation costs are to be audited by the Medicare Administrative Contractors (MACs).

In the paragraphs that follow, we discuss our proposals in the FY 2023 IPPS/LTCH proposed rule. We received no comments on these proposals and are finalizing our proposals without modification.

2. Qualified and Funded Non-Qualified Deferred Compensation Plans (§ 413.99)

In accordance with section 1861(v)(1)(A) of the Act, in the FY 2023 IPPS/LTCH proposed rule (87 FR 28613), we proposed to add a new § 413.99 in subpart F of part 413 of title 42, titled ''Qualified and Funded Non-Qualified Deferred Compensation Plans,'' to establish rules for allowable and non-allowable costs incurred for the plans, by providers of services, under the program. Our proposals, which we discuss in more detail throughout this section of this final rule, set forth general requirements; definitions; requirements for costs of the plans to be allowable under the program; additional requirements for payments to funded defined benefit plans; data and documentation requirements to support payments/contributions to the plans;

and allowable administrative and other costs associated with the plans, including costs related to the Pension Benefit Guaranty Corporation (PBGC).

We received no comments on these proposals and are finalizing our proposals without modification.

3. Statutory Basis, Scope, and Definitions (§ 413.99(a))

In accordance with section 1861(v)(1)(A) of the Act, in the FY 2023 IPPS/LTCH proposed rule (87 FR 28613), we proposed to establish the ''Basis,'' ''Scope,'' and ''Definitions'' of these regulations that determine the allowable and non-allowable costs of the plans under the program at proposed new § 413.99(a)(1), (2), and (3), respectively. Specifically, we proposed at new § 413.99(a)(1) to specify that all payments to providers of services must be based on the ''reasonable cost'' of services covered under Title XVIII in accordance with section 1861(v) of the Act and the regulations in 42 CFR part 413. In addition, we proposed at new § 413.99(a)(2) to specify that this section and § 413.100(c)(2)(vii) will apply to Medicare's treatment of the costs incurred for Qualified and Non-Qualified Deferred Compensation Plans.

CMS has previously defined certain terms related to the program's policies on Deferred Compensation and the plans in sections 2140 through 2142 of PRM–I. In the FY 2023 IPPS/LTCH proposed rule (87 FR 28613), we proposed to codify these definitions, with clarifications where appropriate, at new § 413.99(a)(3). We also proposed to add definitions for several new terms to ensure clarity and consistent application. Specifically, we proposed at new § 413.99(a)(3) to establish, for purposes of § 413.99, definitions for the following terms: *Deferred Compensation, Employee Retirement Income Security Act of 1974 (ERISA), Funded Plan, Non-Qualified Deferred Compensation Plan (NQDC), Non-Qualified Defined Benefit Plan (NQDB), Pension Benefit Guaranty Corporation (PBGC), Qualified Defined Benefit Plan (QDBP), Qualified Defined Contribution or Individual Account Plan (QDCP),* and *Unfunded plan.* The specific definitions we proposed to codify at § 413.99(a)(3) appear in the proposed rule at 87 FR 28648 through 28649.

We received no comments on this proposal and are finalizing this proposal without modification.

4. Principle Requirements (§ 413.99(b))

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28613 through 28614), we proposed to establish at new § 413.99(b) the ''Principle requirements'' that must be satisfied by all Deferred Compensation Plans in order for costs incurred by a provider of services in connection with such plans to be allowable under the program. A formal Deferred Compensation Plan is an agreement between the provider of services and its participating employees, in which the agreeing parties can make contributions to the plan for the exclusive benefit of its participating employees. Proposed § 413.99(b)(1) would specify that amounts be contributed by a provider of services, or an employee of the provider of services, to a Qualified or Non-Qualified Deferred Compensation Plan, established and maintained by the provider of services to provide retirement income to employees or to result in the deferral of income by employees for periods extending to the termination of covered employment or beyond. Contributions or payments made by a provider of services for the benefit of its employees to a Qualified or Non-Qualified Deferred Compensation Plan are allowable when, and to the extent that, such costs are actually incurred by the provider of services and found to be reasonable and necessary under the principles of reasonable cost.

Contracts or agreements between hospital-based physicians and hospitals involve a variety of arrangements under which the physician is compensated by the hospital for the full range of services within the institution. We proposed to include requirements for recognition of the costs incurred to fund the plans for hospital-based physician patient care services and guarantee arrangements for physician emergency room services. Deferred compensation paid for physician services to hospitals and SNFs is part of physician compensation under § 415.60(a) and is directly attributable to an employee's salary. Deferred compensation is salary earned in the current period that is not received until a subsequent period, usually after retirement. Defined Contribution plans and Defined Benefit plans generally specify contributions and benefits as a percentage of employee salary. Deferred compensation based on unallowable compensation is also unallowable. Consistent with the policies in PRM–I, we proposed in § 413.99(b)(2) to specify that costs incurred by a hospital or SNF to fund a Qualified or Non-Qualified Deferred Compensation Plan for a provider-based physician must meet certain requirements to be allowable. These proposed requirements at § 413.99(b)(2)(i) through (iii) would establish that: (i) the allocation of physician compensation costs required under § 415.60 does not attribute the provider-based physician's Deferred Compensation entirely to one category of service and his current compensation to another; (ii) contributions or payments toward the Qualified or Non-Qualified Deferred Compensation Plan do not include any cost excluded from the definition of physician compensation at § 415.60(a); and (iii) the amount of Deferred Compensation does not exceed the amount specified in the agreement required by § 415.60(g).

In situations where the provider is merely acting as the billing agent for the physician whose remuneration is derived from billing for patient care services, the Medicare program will not recognize such remuneration. As a result, these proposed requirements would also specify that an arrangement between a physician and a provider of services under which the physician is reimbursed for patient charges, but the provider of services does the billing as a Deferred Compensation agreement, is not allowed. We proposed to codify this policy at § 413.99(b)(2)(iv).

We proposed to codify at § 413.99(b)(2)(v) that the costs incurred for physician guarantee arrangements for hospital emergency room availability services must also meet the additional requirements that: (1) the terms of both the guarantee arrangement and the Deferred Compensation plan establish the amounts to be included at the beginning of the hospital's cost reporting period; (2) the amount of Deferred Compensation is included in the guaranteed amount; (3) the hospital contributes to the fund established under the Deferred Compensation Plan from its own funds; (4) the amount of Deferred Compensation that is allowable is limited to the amount by which the guarantee, including Deferred Compensation, exceeds the total billed by the hospital to all patients for the physician's patient care services; and (5) when the physician's charges to all patients equal or exceed the amount guaranteed by the hospital, the program does not recognize a Deferred Compensation contribution/payment.

We received no comments on the proposed principle requirements of § 413.99(c) and are finalizing this proposal without modification.

5. Requirements for Non-Qualified and Qualified Deferred Compensation Plans (§ 413.99(c))

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28614 through 28615), we proposed to codify the guidance from sections 2140 through 2142 of PRM–I regarding the requirements that must be

met in order for costs incurred by providers of services to be allowable for inclusion as Deferred Compensation in the Medicare cost report. The requirements vary based on the type of plan established by the provider of services. The plans currently recognized by the program include Deferred Compensation Plans, currently set forth in section 2140 of PRM–I, Qualified Defined Contribution Deferred Compensation Plans set forth in section 2141 of PRM–I, and Qualified Defined Benefit Pension Plans set forth in section 2142 of PRM–I. As discussed previously in section X.A.1. of this final rule, we proposed to codify the definitions of these types of plans and related terms, with clarifications where appropriate, in proposed new § 413.99(a)(3). We proposed to establish at new § 413.99(c) the plan-specific requirements that each type of Qualified or Non-Qualified Deferred Compensation Plan must meet in order for a provider of servicers contributions or payments to the plan to be allowable under the program.

Employer contributions for the benefit of employees under a Deferred Compensation Plan are allowable when, and to the extent that, such costs are actually incurred by the provider or services. Contributions to a funded Deferred Compensation Plan are allowable costs when they are made to the plan, to the extent they fall under the computed limit. Benefits paid for an unfunded Deferred Compensation Plans are allowable costs only when actually paid to the participating employees (or their beneficiaries), and only to the extent considered reasonable.

First, we proposed to codify at § 413.99(c)(1) the requirements for NQDCs, which can be funded or unfunded. Proposed § 413.99(c)(1)(i) would establish that an NQDC must meet the requirements for document compliance and operational compliance set forth in Internal Revenue Code (IRC) section 409A. Proposed paragraph (c)(1)(ii) would specify that a funded NDQC must meet the proposed definition of a Funded Plan in § 413.99(a)(3) and comply with the requirements in proposed § 413.99(c)(5) (discussed later in this section of this final rule). Proposed paragraph (c)(1)(iii) would provide that an unfunded NQDC must meet the definition of an Unfunded Plan as proposed in § 413.99(a)(3), and there must be no constructive receipt of income for employees from the NQDC as a result of contributions made by a provider of services.

Second, we proposed to codify at § 413.99(c)(2) the requirements for QDCPs. Consistent with our existing policies for Defined Contribution Deferred Compensation Plans found in section 2141.1 of PRM–I, proposed paragraph (c)(2)(i) would specify that a QDCP must meet the applicable requirements of ERISA, as amended, and the requirements set forth in IRC section 401(a), and, if applicable, section 401(k). In addition, proposed paragraph (c)(2)(ii) would specify that a QDCP must meet the proposed definition for a Funded Plan in § 413.99(a)(3) and comply with the requirements in proposed § 413.99(c)(5).

Third, we proposed to codify at § 413.99(c)(3) the requirements for QDBPs. Specifically, proposed § 413.99(c)(3)(i) would establish that a QDBP must meet the applicable requirements of ERISA, as amended, and the requirements for a QDBP under IRC section 401(a). Proposed paragraph (c)(3)(ii) would specify that a QDBP must meet the definition of a Funded Plan as proposed in § 413.99(a)(3) and comply with the requirements in proposed § 413.99(c)(5).

Fourth, we proposed to codify at § 413.99(c)(4) the requirements for NQDBs, which may be funded or unfunded. Proposed § 413.99(c)(4)(i) would establish that an NQDB must meet the requirements for document compliance and operational compliance set forth in Internal Revenue Code (IRC) section 409A. Proposed paragraph (c)(4)(ii) would specify that a funded NQDB must meet the definition of a Funded Plan as proposed in § 413.99(a)(3) and comply with the requirements in proposed § 413.99(c)(5). Proposed paragraph (c)(4)(iii) would provide that an unfunded NQDB must meet the definition of an Unfunded Plan as proposed in § 413.99(a)(3), and there must be no constructive receipt of income for employees from the NQDC as a result of contributions made by a provider of services.

We proposed to codify at § 413.99(c)(5) certain requirements for Funded Plans. We proposed to establish at paragraph (c)(5)(i) the types of funding mechanisms that Funded Plans must use in order for provider of services contributions and employee contributions to such plans to be included in allowable costs. Specifically, a Funded Plan would be required to use either to purchase an insured plan with a commercial insurance company, to establish a custodial bank account, or to establish a trust fund administered by a trustee. Proposed paragraph (c)(5)(ii) would codify our longstanding policy, set forth in section 2140.3.B of PRM–I, disallowing the use of an ordinary life insurance contract as a funding mechanism for a Funded Plan. Specifically, proposed paragraph (c)(5)(ii) would specify that the purchase of an ordinary life insurance contract (for example, whole life, straight life, or other) is not a deferral of compensation and is not recognized as a funding mechanism, even where it is convertible at the normal retirement date specified in the policy to an annuity payable over the remaining life of the employee. Proposed paragraph (c)(5)(iii) would establish that, regardless of the funding mechanism utilized, all provider of services and employee contributions to the fund established under the Deferred Compensation Plan and income therefrom must be used for the sole benefit of the participating employees.

The proposed requirements for a Funded Plan are based on the generally accepted definition of a Funded Plan, along with existing CMS policies on the funding of Deferred Compensation Plans found in section 2140.3 of PRM–I.

We received no comments on the proposed requirements of § 413.99(c) for Non-Qualified and Qualified Deferred Compensation plans and are finalizing this proposal without modification.

6. Recognition of Contributions or Payments to Qualified and Non-Qualified Deferred Compensation Plans (§ 413.99(d))

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28615 through 28616), at proposed § 413.99(d), we proposed to codify rules and requirements that determine when payments or contributions by a provider to Qualified or Non-Qualified Deferred Compensation Plans that meet the applicable plan-specific requirements at proposed § 413.99(c) are recognized and included in allowable costs under the program. In general, the rules in proposed § 413.99(d) vary depending on whether a plan is qualified or non-qualified. In addition, certain special rules apply to contributions to QDBPs and NQDBs that are deposited into trusts.

First, for unfunded Deferred Compensation Plans (which include unfunded NQDBs), we proposed to codify at proposed § 413.99(d)(1)(ii) that payments made to such plans are included in allowable costs only during the cost reporting period in which an actual payment is made to the participating employees (or their beneficiaries) and only to the extent considered reasonable in accordance with § 413.100(c)(2)(vii)(A). This proposed requirement incorporates the existing regulatory requirement for

payments to unfunded Deferred Compensation Plans at § 413.100(c)(2)(vii)(A), to aid the reader in understanding related policies that appear in other sections of this part that affect unfunded NQDCs and unfunded NQDBs.

Second, regarding certain funded Deferred Compensation Plans (specifically funded Defined Contribution Plans, but excluding QDBPs and funded NQDBs), we proposed to include at § 413.99(d)(1)(ii) a cross reference to § 413.100(c)(2)(vii)(B), which requires that accrued costs related to matching or non-elective contributions to a funded Deferred Compensation Plan must be liquidated within 1 year after the end of the cost reporting period in which the liability is incurred. Under § 413.100(c)(2)(viii)(B), an extension, not to exceed 3 years beyond the end of the cost reporting year in which the liability was incurred, may be granted for good cause if the provider of services, within the 1-year time limit, furnishes to the contractor sufficient written justification for non-payment of the liability. Applying this requirement to QDCPs is consistent with § 413.100(c)(2)(vii)(B) and with policies established in section 2141.2 of PRM–I.

Third, contributions into a protected trust for QDBPs and funded NQDBs are allowable. We require that these assets be protected solely for the plan participants and to pay reasonable plan administrative expenses. Contributions or payments must be made by the provider into a protected trust and accounted for on a cash basis. For these plans, we proposed to establish at § 413.99(d)(1)(iii) that contributions by providers must satisfy the following four requirements to be allowable: first, the contributions must be paid to the plan participants or the plan trust; second, contributions are accounted for on a cash basis; third, money refunded from a plan must be treated as a negative contribution; and fourth, the allowable cost must be computed in accordance with the calculation defined in § 413.100(c)(2)(vii)(D). We described each of these proposed requirements in greater detail in the paragraphs that follow.

First, we proposed to establish at § 413.99(d)(1)(iii)(A) that QDBP or funded NQDB contributions are found to have been incurred only if paid directly to participants or beneficiaries under the terms of the plan or to the QDBP or NQDB. Proposed paragraph (d)(1)(iii)(A) codifies our existing policy, which is described in section 2142.6.A of PRM–I. Section 2142.6 states that provider contributions or payments made to a defined benefit pension plan are allowable only to the extent that costs are actually incurred by the provider. Such costs are found to have been incurred only if paid directly to participants or beneficiaries under the terms of the plan or paid to a pension fund which meets the applicable tax qualification requirements under IRC section 401(a).

Second, we proposed to codify at § 413.99(d)(1)(iii)(B) the existing regulatory requirement at § 413.100(c)(2)(vii)(D) for contributions to a QDBP or funded NQDB. Specifically, proposed § 413.99(d)(1)(iii)(B) would require that payments to a QDBP or funded NQDB for a cost reporting period be measured on a cash basis. A contribution or payment would be deemed to occur on the date it is credited to the fund established for the QDBP or funded NQDB, or for provider of services payments made directly to a plan participant or beneficiary, on the date the provider of services account is debited.

Third, we proposed to clarify the treatment of pension contributions when a QDBP or funded NQDB is terminated at § 413.99(d)(1)(iii)(C) as payments/contributions made to fully fund a terminating QDBP or funded NQDB are to be included as funding on the date they are paid. Excess assets withdrawn from a QDBP or funded NQDB are to be treated as negative contributions on the date that they are withdrawn. We believe our proposal to recognize negative contributions by reference to the date of withdrawal provides greater clarity than the standard under our current guidance under section 2140.3 of PRM–I, which refers to the ''year of plan termination,'' which is less specific and subject to interpretation.

Fourth, we proposed to specify at § 413.99(d)(1)(iii)(D) that QDBP and funded NQDB costs and limits are computed in accordance with the existing regulatory requirements at § 413.100(c)(2)(vii)(D). For purposes of determining the QDBP or funded NQDB cost limit under § 413.100(c)(2)(vii)(D)(*2*), we propose that provider of services contribution payments for each applicable cost reporting period shall be determined on a cash basis in accordance with proposed § 413.99(d)(1)(iii)(B), without regard to any limit determined for the period during which the contributions were made, and excluding any contributions deposited in a prior period and treated as carry forward contributions. We proposed that the averaging period used to determine the QDBP or funded NQDB cost limit shall be determined without regard to a provider of services period of participation in the Medicare program. Periods that are not Medicare cost reporting periods (for example, periods prior to the hospital's participation in the Medicare program) shall be defined as consecutive twelve-month periods ending immediately prior to the provider of services initial Medicare cost reporting period. We proposed that the averaging period used to determine the QDBP or funded NQDB cost limit shall exclude all periods ending prior to the initial effective date of the plan (or a predecessor plan in the case of a merger). Lastly, we proposed that in general, the current period defined benefit cost and limit shall be computed and applied separately for each QDBP or funded NQDB offered by a provider of services. In the case of a plan merger, the contribution payments made by a provider of services to a predecessor QDBP or funded NQDB and reflected in the assets subsequently transferred to a successor plan shall be treated as contribution payments made to the successor plan.

In the FY 2012 IPPS/LTCH PPS final rule, we established separate methodologies for measuring pension costs for Medicare cost-finding purposes (76 FR 51693 through 51697) and for purposes of updating the hospital wage index (76 FR 51586 through 51590). Under the methodology we established for the wage index, the pension costs that are to be included in the wage index equal a hospital's average cash contributions deposited to its defined benefit pension plan over a 3-year period or, if less than a 3-year period, the number of years that the hospital has sponsored a defined benefit plan. The 3-year average was centered on the base cost reporting period for the wage index. For example, the FY 2013 wage index is based on Medicare cost reporting periods beginning during Federal FY 2009 and reflects the average pension contributions made in hospitals' cost reporting periods beginning during Federal FYs 2008, 2009, and 2010. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49505 through 49508), we modified the policy such that the 3-year average is based on pension contributions made during the base cost reporting period plus the prior 2 cost reporting years. For example, the FY 2017 wage index is based on Medicare cost reporting periods beginning during Federal FY 2013. Therefore, the FY 2017 wage index reflects the average pension contributions made in hospitals' cost

reporting periods beginning during Federal FYs 2011, 2012, and 2013 (rather than Federal FYs 2012, 2013, and 2014 under the prior policy established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)). While the QDBP cost for cost-finding purposes is computed using the cost period annual contributions limited by a cap (as codified in § 413.100(c)(2)(vii)(D)), the wage index QDBP cost is a 3-year average of annual plan contributions without adjustment or cap.

We received no comments on the proposed recognition under § 413.99(d) of contributions or payments to Qualified and Non-Qualified Deferred Compensation Plans and are finalizing this proposal without modification.

7. Documentation Requirements (§ 413.99(e))

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28616 through 28617), we proposed to codify at § 413.99(e) that a provider of services must maintain and make available upon request documentation to substantiate the costs incurred for the plans included in its Medicare cost report. These proposed requirements for documentation are based on the existing regulatory requirements at § 413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under the program.

In addition, these requirements are based in part on the policy established when CMS revised the calculation for a QDBP and funded NQDB in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51693 through 51697). Section 2142.5.F of PRM–I states that the provider must have available data to show the amount(s) and date(s) of contribution payments made to a defined benefit pension plan during the current reporting period and any applicable prior periods. If the pension costs included in the cost report for a period differ from the pension contribution payments made during the reporting period (for example, as a result of carry forward contributions), the provider must also have data available to track and reconcile the difference.

Specifically, we proposed at § 413.99(e) that documentation must be maintained by the provider of services in accordance with § 413.20 to substantiate the allowability of the payments or contributions to Qualified or Non-Qualified Deferred Compensation Plans (or both) that it has included in its cost reports. With respect to *required documentation,* we proposed to specify at § 413.99(e)(1) that the provider of services must maintain and make available, upon request from the contractor or CMS, certain specified documentation, to substantiate the allowability of payments or contributions made by the provider of services to a Qualified or Non-Qualified Deferred Compensation Plan. Under proposed § 413.99(e)(1), the following documentation would be required: documentation that demonstrates that the provider of services is in compliance with IRC section 409A and IRC section 409A(a), and if applicable IRC section 457; ledger accounts/account statements for each plan participant noting current year deferrals, distributions, and loans, including any deferral election forms completed by employees, any change requests, and the approval of such requests; documentation that demonstrates the amount(s) and date(s) of actual payment/contributions made to the Non-Qualified or Qualified Deferred Compensation Plan during the current cost reporting period; Schedule SB of Form 5500 (tri-agency form (Department of Labor (DOL), Internal Revenue Service (IRS), PBGC) that plans file with the DOL's ''EFAST'' electronic filing system. The ''Form 5500'' is the Annual Return/Report of Employee Benefit Plan for a QDBP for the current cost reporting period, or any applicable prior periods; and, in the case of a system wide (multiple employer) plan, the home office shall identify the contributions attributed to each participating provider of services. If the costs included in the cost report for a period differ from the contributions made during the reporting period (for example, as a result of carry forward contributions), the provider of services must also have data available to track and reconcile the difference.

We also proposed to establish at § 413.99(e)(2) that the following additional documentation must be made available, upon request by the contractor or CMS, to substantiate the allowability of payments or contributions made by a provider of services to a Qualified or Non-Qualified Deferred Compensation Plan: the plan document, the trust document and all amendments related to the current cost reporting period; if applicable, any Form 5330, Return of Excise Taxes Related to Employee Benefit Plans, for the cost reporting period; supporting documents for all plan assets and liabilities, such as broker's statements, bank statements, insurance contracts, loan documents, deeds, etc., and verification of how assets are valued; trustee or administrator reports; ledgers; journals; trustee, administrator and investment committee minutes; certified audit report; and other financial reports for the trust. Any other financial reports, including receipt and disbursement statements, a detailed income statement and a detailed balance sheet; and, for each covered QDBP, documentation of the certified premium information and payments to the PBGC.

We received no comments on the proposed documentation requirements of § 413.99(e) and are finalizing this proposal without modification.

8. Administrative and Other Costs Associated With Qualified and Non-Qualified Deferred Compensation Plans (§ 413.99(f))

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28617), in proposed § 413.99(f), we proposed to codify our current policies, as set forth in sections 2140, 2141, and 2142 of PRM–I, regarding the treatment of certain administrative and other costs related to Deferred Compensation Plans as allowable or non-allowable under the program. In the paragraphs that follow, we discuss our proposed treatment of various administrative costs related to Deferred Compensation Plans. First, we proposed to establish at § 413.99(f) that the provider of services shall file a cost report required under §§ 413.20 and 413.24(f) that is consistent with the proposed policies set forth in proposed § 413.99.

We received no comments on this proposal and are finalizing this proposal without modification.

a. Trustee and Custodial Fees

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28617), we proposed to codify at § 413.99(f)(1) that reasonable trustee or custodial fees, including PBGC premiums, paid by the provider of services are allowed as an administrative cost, except where the plan provides that such fees are paid out of the corpus or earnings of the fund. Fees paid out of the corpus or earnings of the fund would not be allowed, based on the rationale that, because contributions into the plan trust pay for benefits and expenses that are paid from the trust, that means administrative costs paid out of the plan trust have already been accounted for through the allowance of contributions made by the provider of services. This proposed provision would codify our current policy, which is set forth in section 2140.3.B.1.d of PRM–I.

We received no comments on this proposal and are finalizing this proposal without modification.

b. Vested Benefits

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28617), we proposed to codify at § 413.99(f)(2) that the forfeiture of an employee's benefits for cause (as defined in the plan) is recognized as an allowable cost provided that such forfeited amounts are used to reduce the provider of services contributions or payments to the plan during the cost reporting period in which the forfeiture occurs. This proposed provision would codify our policy on the effects of a forfeiture of vested benefits on the plan costs that are allowable under the program, as set forth at section 2140.3.D of PRM–I, with the added clarification that the reduction must occur in the cost reporting period in which the forfeiture occurs.

We proposed to codify at § 413.99(f)(3) our existing policy on the effects of employees' termination of participation in a plan before their rights are vested in the contributions/payments to the plan that are allowable under the program. Specifically, proposed § 413.99(f)(3) would specify that if an employee terminates participation in the Deferred Compensation Plan before their rights are vested, the applicable non-vested contributions/payments cannot be applied to increase the benefits of the surviving participants. Instead, the non-vested contributions/payments should be used to reduce the provider of services contributions/payments to the Deferred Compensation Plan, in the cost reporting period wherein the employee terminated participation in the Deferred Compensation Plan. Otherwise, the contributions/payments made by the provider of services must be applied to reduce the subsequent contributions/payments to the Deferred Compensation Plan in the next cost reporting period. If subsequent provider of services contributions/payments to the Deferred Compensation Plan are not made, then provider of services costs will be reduced by the contractor to the extent of such non-vested funds.

We received no comments on this proposal and are finalizing this proposal without modification.

c. DOL, IRS, and PBGC Penalties

Providers of services who maintain a Deferred Compensation Plan are required to comply with regulatory requirements related to the plan that are established by the Department of Labor (DOL), the IRS and the PBGC. Where providers of services fail to follow these requirements, a penalty may be levied. For example, the IRS levies an excise tax when payments are not timely filed. Section 1861(v)(8) of the Act sets forth items unrelated to patient care that are not considered reasonable under the program. In other words, these items are unallowable, and therefore cannot be included in the allowable costs of the provider of services. One of these items is the cost for fines and penalties resulting from violations of Federal, State, or local laws. Accordingly, in the FY 2023 IPPS/LTCH proposed rule (87 FR 28617), we proposed at § 413.99(f)(4) to specify that if the provider of services is assessed an excise tax or other remedy by DOL or IRS or PBGC for failure to follow the DOL, IRS, or PBGC requirements under ERISA, or any other penalty fee or penalty interest applicable to its Deferred Compensation Plan, the associated cost is unallowable, in accordance with section 1861(v)(8)(iv) of the Act.

We received no comments on this proposal and are finalizing this proposal without modification.

d. Loans Made From a Deferred Compensation Plan

Under our current policy, as set forth in section 2140.3.C of PRM–I providers of services are able to make a loan to themselves out of either corpus or income from their Qualified or Non-Qualified Deferred Compensation Plan on the conditions that the fund receive adequate security and a reasonable rate of interest on the loan. This existing policy is inconsistent with ERISA section 406 (29 U.S.C. 1106(1)(B)) which specifically prohibits lending of money or other extension of credit between the plan and a party in interest, unless found to be excepted under 29 U.S.C. 1108. The definition of a ''party in interest'' includes an employer any of whose employees are covered by such plan. The same provision exists in the IRC at 26 U.S.C. 4975. We believe that the policy we proposed to codify in new § 413.99 should reflect these provisions in ERISA and the IRS rules that are designed to protect Deferred Compensation Plans and the plans' participants and beneficiaries. Accordingly, in the FY 2023 IPPS/LTCH proposed rule (87 FR 28617), we proposed at § 413.99(f)(5) to specify that a provider of services cannot make a loan to itself from a Deferred Compensation Plan where ERISA or IRS rules prohibit such a transaction, except where specifically excepted. In cases where an exception applies, our existing policy on allowable interest expense at § 413.153 continues to apply.

We received no comments on this proposal and are finalizing this proposal without modification.

e. Termination/Discontinuation of a Deferred Compensation Plan

Sections 2140.3.D and 2141.3.D of PRM–I set forth CMS's policy on the effect of a provider of services declining to vest its outstanding required contributions/payments as a result of a termination, in full or in part, or a discontinuation of contributions or payments to a Deferred Compensation Plan. Under this policy, we proposed n the FY 2023 IPPS/LTCH proposed rule (87 FR 28617 through 28618), to codify at § 413.99(f)(6), where the provider of services declines to vest its outstanding required contributions/payments (that is, matching and non-elective or both) to a Deferred Compensation Plan, as a result of a termination, in full or in part, or a discontinuation of contributions or payments to a Deferred Compensation Plan, then the provider of services total outstanding required contributions or payments to the Deferred Compensation Plan during the cost reporting period wherein such termination is initiated cannot be included in the provider of services allowable cost for the cost reporting period in which the termination is initiated, nor any future period.

We received no comments on this proposal and are finalizing this proposal without modification.

f. Required Offset Against Interest Expense

In section 2140.3.D of PRM–I, CMS has established a policy that investment income earned on a fund after its termination but prior to liquidation of the fund's assets and distribution to the provider is offset against the provider's allowable interest expense. In the FY 2023 IPPS/LTCH proposed rule (87 FR 28618), we proposed to adopt the current policy in section 2140.3 of PRM–I at proposed § 413.99(f)(7), which would state that investment income earned on a Deferred Compensation Plan after its termination but prior to liquidation of the plan's assets and distribution to the provider of services must be offset against the provider of services allowable interest expense under § 413.153.

We received no comments on this proposal and are finalizing this proposal without modification.

g. Treatment of Residual Assets Following Termination of a Funded Plan

In section 2140.3.D of PRM–I, CMS has established a policy describing how residual assets arising from the termination of a funded plan are to be handled on the Medicare cost report. In

the FY 2023 IPPS/LTCH proposed rule (87 FR 28618), we proposed to adopt the current policy, as it appears in section 2140.3.D of PRM–I, at new § 413.99(f)(8). Specifically, we proposed that § 413.99(f)(8) would specify that residual assets arising from the termination of a funded plan must be recouped in the year of the plan termination only against the cost center(s) in which the provider of services reported its plan contributions/payments, usually the administrative and general cost center. Residual assets exceeding the amount in the administrative and general (or other) cost center are not further offset in the current or subsequent years. The Medicare share of the reversion is based on the Medicare utilization rate in the year the reversion occurs (or the year the actuarial surplus is determined), and not Medicare's utilization in the years the contributions to the plan were made.

We received no comments on this proposal and are finalizing this proposal without modification.

9. Treatment of Costs Associated With the Pension Benefit Guaranty Corporation (PBGC) (§ 413.99(g))

Since 1974, the PBGC has protected retirement security and the retirement incomes of over 33 million American workers, retirees, and their families in private sector defined benefit pension plans. A Qualified Defined Benefit Plan (defined previously as a QDBP) provides a specified monthly benefit at retirement, often based on a combination of salary and years of service. The PBGC was created by ERISA to encourage the continuation and maintenance of private sector defined benefit pension plans, provide timely and uninterrupted payment of pension benefits, and keep pension insurance premiums at a minimum.

General tax revenues do not fund the PBGC Single-Employer Program. The PBGC collects insurance premiums from employers that sponsor insured pension plans, earns money from investments, and receives funds from pension plans it takes over (see *https://www.pbgc.gov/about/how-pbgc-operates*).

Providers of services who offer a QDBP may incur costs related to the PBGC premiums. The proposed regulations outlined in this section of this final rule establish which costs incurred by providers of services who maintain a QDBP and pay premiums for basic benefits to the PBGC are allowable under the program. We proposed to include these provisions on the treatment of costs associated with the PBGC in paragraph (g) of proposed § 413.99.

In 29 U.S.C. 1306 the schedule for the premium rates, and the bases for application of those rates are set forth. Under 29 U.S.C. 1306, premiums are established for basic benefits, non-basic benefits, and reimbursement for uncollectible withdrawal liability. In the FY 2023 IPPS/LTCH proposed rule (87 FR 28618), we proposed at § 413.99(g)(1) that PBGC premiums and costs paid out of the corpus or earnings of the trust are included in the contributions allowed by § 413.99(d)(3)(ii), and therefore are not allowable as separate costs. We note, in the proposed rule we inadvertently made a typographical error and referred to § 413.99(d)(3)(ii) when we intended to refer to § 413.99(d)(1)(iii)(A). We also proposed at § 413.99(g)(2) that the amount of PBGC premiums paid for basic benefits (that is, flat rate or variable, excluding amounts paid out of the corpus or earnings of the trust) by a provider of services who sponsors a QDBP are allowable under the program. Similar to allowance of Administrative Costs as stated in proposed § 413.99(f)(1), while PBGC premiums are an allowable cost, they are not allowed if they are paid from the plan trust.

In 29 CFR part 4050, the rules for PBGC's program that holds retirement benefits for missing participants and beneficiaries of terminated retirement plans and pays those benefits to participants and beneficiaries when found, are provided. A Missing Participant is a former employee of a provider of services who has a liability remaining with the plan but cannot be located or is unresponsive when the plan terminates and closes out. Transfers of funds to the PBGC by the provider of services to cover this liability under the PBGC Missing Participant Program are allowable as long as they are not paid out of the corpus or earnings of the trust. In the FY 2023 IPPS/LTCH proposed rule (87 FR 28618), we proposed at new § 413.99(g)(3) that the total amount paid to the PBGC by a provider of services who sponsors a QDBP (excluding amounts paid out of the corpus or earnings of the trust) of the benefit transfer amount (see 29 CFR 4050.103(d)) for all missing participants or beneficiaries of the QDBP is allowable under the program.

After entering into a trusteeship agreement with the employer or after receiving an order issued by a U.S. district court approving termination, the PBGC guarantees employee plan benefits will be paid up to a certain limit if the QDBP has insufficient assets as part of a Distress Termination (as described in 29 CFR part 4041) or as part of a PBGC-initiated termination under 29 U.S.C. 1342. In the FY 2023 IPPS/LTCH proposed rule (87 FR 28618), we proposed at § 413.99(g)(4) that for terminated plans with insufficient assets to pay all of the plan benefits, where the PBGC guarantees the payment of vested benefits up to limits defined by law, only contributions to the QDBP made by a provider of services are allowable. Benefits paid to the participants and beneficiaries of the QDBP by the PBGC are unallowable.

In 29 CFR part 4047, PBGC is given the authority to restore a plan from terminated status to ongoing. Contributions and benefits paid by the provider of services to the PBGC or the plan or its participants and beneficiaries are allowable in this situation. In the FY 2023 IPPS/LTCH proposed rule (87 FR 28618), we proposed at § 413.99(g)(5) that where the PBGC issues or has issued a plan restoration order as described in 29 CFR part 4047, the amounts that the provider of services repays to the PBGC for guaranteed benefits and related expenses under the plan while the plan was in terminated status, and any administrative costs assessed by the PBGC, excluding penalties, are allowable.

We received no comments on the proposed treatment of costs associated with the PBGC under § 413.99(g) and are generally finalizing this proposal without modification, except we are revise the proposed regulation text at § 413.99(g)(1) so that the erroneous reference to § 413.99(d)(3)(ii) is corrected in the finalized regulation text and instead refers to § 413.99(d)(1)(iii)(A).

B. Condition of Participation (CoP) Requirements for Hospitals and CAHs To Continue Reporting Data for COVID–19 and Influenza After the PHE Ends as Determined by the Secretary

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the state Medicaid agency, as appropriate. Hospitals (all hospitals to which the requirements of 42 CFR part 482 apply, including short-term acute care hospitals, LTC hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals) and CAHs seeking to be Medicare and Medicaid providers of services under 42 CFR part 485, subpart F, must be certified as meeting Federal participation requirements. Our conditions of participation (CoPs), conditions for coverage (CfCs), and requirements set out the patient health

and safety protections established by the Secretary for various types of providers and suppliers. The specific statutory authority for hospital CoPs is set forth in section 1861(e) of the Act; section 1820(e) of the Act provides similar authority for CAHs. The hospital provision at section 1861(e)(9) of the Act authorizes the Secretary to issue any regulations he or she deems necessary to protect the health and safety of patients receiving services in those facilities; the CAH provision at section 1820(e)(3) of the Act authorizes the Secretary to issue such other criteria as he or she may require. The CoPs are codified in the implementing regulations at part 482 for hospitals, and at 42 CFR part 485, subpart F, for CAHs.

Our CoPs at § 482.42 for hospitals and § 485.640 for CAHs require that hospitals and CAHs, respectively, have active facility-wide programs, for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases and for the optimization of antibiotic use through stewardship. Additionally, the programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the required hospital and CAH programs must also be addressed in coordination with facility-wide quality assessment and performance improvement (QAPI) programs.

Infection prevention and control is a primary goal of hospitals and CAHs in their normal day-to-day operations, and these programs have been at the center of initiatives taking place in hospitals and CAHs during the PHE for COVID–19. Our regulations at §§ 482.42(a)(3) and 485.640(a)(3) require infection prevention and control program policies to address any infection control issues identified by public health authorities. We proposed to revise the hospital and CAH infection prevention and control and antibiotic stewardship programs CoPs to extend the current COVID–19 reporting requirements and to establish new reporting requirements for any future PHEs related to a specific infectious disease or pathogen.

Specifically, we proposed to revise the COVID–19 and Seasonal Influenza reporting standards for hospitals and CAHs (at §§ 482.42(e) and (f); and 485.640(d) and (e), respectively) to require that, beginning at the conclusion of the current COVID–19 PHE declaration and continuing until April 30, 2024, a hospital (or a CAH) must electronically report information about COVID–19 and seasonal influenza in a standardized format specified by the Secretary. In addition, we proposed additional requirements to address future PHEs related to infectious diseases at §§ 482.42(g) and 485.640(f), for hospitals and CAHs respectively. Specifically, when the Secretary has declared a PHE, we proposed to require hospitals and CAHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. We noted that the proposed requirements of this section would apply to local, state, and national PHEs as declared by the Secretary.

In the proposed rule, we highlighted the various interim final rules with comment (IFC) that currently require hospitals and CAHs to report important data critical to support the fight against COVID–19 and noted that these requirements are both tied to the current PHE (meaning they would no longer be required post-PHE) and emphasized that COVID–19 reporting, by all hospitals and CAHs, have been, and continue to be, important in supporting surveillance of, and response to, the PHE for COVID–19. We stressed that such reporting requirements are necessary for CMS to monitor whether individual hospitals and CAHs are appropriately tracking, responding to, and mitigating the spread and impact of viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential on patients, the staff who care for them, and the general public and the important role that such reporting plays when considering future planning. Additionally, we noted our concern that current reporting, while appropriately focused on the current COVID–19 pandemic, are too limited in scope for potential future use and noted that we are considering ways to ensure a more flexible regulatory framework to promote a nimble and informed response to the next potential pandemic or epidemic, so that we are able to immediately respond to the situation at hand. We refer readers to the FY 2023 IPPS proposed rule for this detailed discussion (87 FR 28618–28622).

In response to the proposed rule, we received approximately 757 public comments that specifically addressed the proposals to continue COVID–19-related data reporting and to establish reporting in the event of a future PHE declaration involving an infectious disease. Commenters included individuals, health care professionals and corporations, national associations, health department and emergency management professionals, and individual facilities that would be impacted by the regulation. We have organized our responses to the comments as follows: (1) general comments, (2) comments focused on the proposals for continued COVID–19-related data reporting, and (3) comments pertaining to the proposals for data reporting in the event of a future PHE declaration. We note that for many comments, CMS was unable to discern if the content was applicable to both proposals or specific to either the proposals for continued COVID–19-related reporting or future data reporting for a declared PHE involving an infectious diseases. We address these comments as general comments. To the extent possible, in those instances where commenters clearly referenced specific requirements in the proposals for either continued COVID–19-related reporting or reporting in the event of a future PHE, we address those comments in the applicable section. Comments related to the collection of information requirements and burden estimates are addressed in sections XII.B.10 and XII.H.11, ''Collection of Information Requirements'' and ''Regulatory Impact Analysis'' of this final rule, as appropriate.

A. General Comments

Comment: Several commenters agreed with our goal to ensure patient health and safety by continuing and establishing a flexible framework for data-driven surveillance and response for COVID–19 and future PHEs involving infectious diseases, respectively. Commenters stated that although collecting and reporting data may consume resources and increase demands on staff, such data are important for establishing and maintaining situational awareness during a PHE and beyond. They noted that these data are critical and used in decision making at the local, state, and federal levels. In addition, while these commenters noted the increased demands experienced by health care facilities and their staff during the COVID–19 PHE, they shared that efforts to recover and resume normal operations are well under way and re-enforced their commitment to providing the highest quality and safe level of care to patients at all times.

Response: We appreciate the support from commenters. We agree that data are critical for monitoring the spread of infectious diseases, informing research and guidance development by government and non-governmental

entities, and responding during and after a public health emergency. We commend health care facilities and their staff for their efforts throughout the COVID–19 pandemic and recovery, and we are also committed to ensuring high quality and safe care to patients.

Comment: While several commenters supported the overall policy goal, many commenters disagreed with our approach to achieve a flexible regulatory framework for data-driven surveillance and response for COVID–19 and future infectious diseases in the event of a PHE declaration. Commenters noted that these proposals would place undue burden on facilities, and particularly during and/or directly after PHEs, when patient care demands and stress and burnout among staff are increased. Some commenters stated the proposed data categories reflected a high level of detail that would be burdensome to collect and report thereby negatively impacting the accuracy of the data and taking time away from patient care, infection prevention and control, and quality improvement activities. Commenters also raised concerns regarding duplicative reporting and encouraged increased coordination at the local, state, and federal level to ease the burden on providers and limit the need to report the same information through multiple streams. Commenters also suggested reviewing the use case for each data category and eliminating those that are not providing valuable information. A few commenters stated that more reimbursement would be needed to support any additional reporting requirements. Others suggested that incentives for reporting data would be helpful.

Response: We understand the burden concerns expressed by commenters. As indicated in the proposed rule, CMS recognizes that the health and safety benefits associated with any reporting requirements must be carefully weighed against the potential burden they impose on facility operations—particularly in situations, like a public health emergency, where staff resources are stretched. We appreciate the comments about reimbursement and incentives; however, reimbursement and incentives are outside of the scope of the CoPs. As suggested by the commenters, we reviewed the use case for each data category, and we discuss this in greater detail in sections B and C. As with the current COVID–19 reporting required during the ongoing PHE, CDC and ASPR are working with states and other jurisdictions for the continuation of COVID–19-related reporting to ensure that states have access to the data reported directly to the federal government and that jurisdictions so inclined can continue to report on behalf of the hospitals within their jurisdictions. According to ASPR, approximately half of the states currently submit data on behalf of the hospitals in their jurisdictions and many have expressed their interest in continuing this capability. CDC, CMS, and ASPR concur and will continue to leverage this capability—where desired by jurisdictions—so that they may receive the data directly from hospitals to fulfill local jurisdictional reporting requirements and then pass the data to the federal government to alleviate the burden of hospitals reporting to both state health departments and the federal government.

Comment: Many commenters noted the significant administrative burden associated with manual entry, configuration, and submission of required data elements, and most agreed that greater automation of the reporting enterprise would be critical to minimizing future hospital burden. A few of these commenters also believed that, given widespread adoption of certified EHR technologies and associated interoperability standards, such automation was within reach for most hospitals. The majority, however, shared concern about the extent to which the technical and technological architecture to support automated, electronic reporting was in place—or would be soon, given the complex array of systems from which hospitals have to pull and assemble required data. These commenters noted that small, rural hospitals and CAHs in particular often lack the resources and IT expertise to establish and maintain the necessary system interfaces. Most commenters focused more on the capabilities necessary for automated data reporting, while some commenters focused on specific systems for data reporting. Specifically, some commenters recommended use of NHSN as a single pathway for data reporting and indicated that this would streamline reporting guidance and the systems for submitting data. Some commenters suggested that the data reporting pathways currently in place for the COVID–19 PHE should remain available for continued COVID–19-related reporting after the PHE ends and for reporting in the event of a future PHE declaration. These commenters noted that changing reporting systems requires modifying workflows and making these changes would increase burden.

Response: We thank commenters for their feedback and agree that greater automation of the reporting enterprise will greatly reduce burden on providers. We expect reporting to become increasingly automated and real-time as data systems and standards continue to mature and become more interoperable. As noted in the proposed rule, the CDC is investing in increasing the automation capabilities of surveillance systems, like the NHSN, and their ability to connect with other data submission techniques, vendors, and systems (87 FR 28622). We look forward to continuing the work in this space and are excited about the future possibilities as we continue efforts to protect and ensure the health and safety of patients.

Comment: Some commenters stated there was a lack of transparency in why CMS would need the data, who would use the data, and how the data would be used. These commenters also indicated that there should be a bi-directional flow of the information reported and that the data should be accessible to all health partners to both increase transparency and inform emergency management efforts.

Response: As CMS noted in the proposals, the proposed rule aimed to minimize data reporting while maintaining transparency [1160] and ensuring that public health agencies, researchers, and the public have sufficient awareness [1161] of overall health system capacity amid evolving epidemiological conditions in order to rapidly direct preventive and response actions. In addition, NHSN provides ready access to data to state and many local public health agencies for the facilities in their jurisdictions via their NHSN accounts and contributes aggregate data to multiple public-facing platforms, including HHS Protect and CMS Care Compare. For example, the COVID–19-related data pertaining to bed census and occupancy, vaccination of staff, and PPE supplies reported by hospitals and CAHs throughout the COVID–19 PHE has been publicly posted in aggregate on a regular basis on HHS Protect and/or NHSN websites.

Requiring the collection of the data supports our responsibility and commitment to protect the health and safety of hospital and CAH patients. These data would allow CMS to monitor whether individual hospitals and CAHs were appropriately tracking, responding to, and mitigating the impact on patients, the staff who care for them, and the general public. A streamlined approach will greatly assist government leaders in tracking, identifying new

[1160] *https://obamawhitehouse.archives.gov/the-press-office/2013/05/09/executive-order-making-open-and-machine-readable-new-default-government-*

[1161] *https://digital.gov/open-data-policy-m-13-13/*

threats, and ultimately inform decision-making, resource allocation, and the ability to inform a coordinated response effort across the nation. For example, during the COVID–19 PHE, the data collected and reported by hospitals and CAHs enabled CMS, in partnership with CDC and ASPR, to monitor the ability of facilities to provide safe care for patients by determining the number of COVID–19 patients being cared for in facilities; the amount of resources facilities were using; and facilities' continued capacity to provide safe care based on these factors. Throughout the COVID–19 pandemic, HHS and state and local agencies used these data to provide resources (such as PPE, staffing, strike teams, financial resources) to hospitals to ensure safe care and used these data to update guidance on the provision of care to patients during periods of scarce staffing, scarce PPE, and limited hospital capacity.

Comment: In response to our request for strategies to support a smooth transition, several commenters suggested implementation approaches that CMS could take to support compliance with the proposed reported policies. Commenters emphasized that the data definitions across facility types and different reporting organizations need to be clearly defined and consistent. These commenters noted that as an example, for healthcare worker COVID–19 vaccination data, the definition of a ''week'' is different depending on to which organization the data are being reported. Commenters stated that providing education to facilities on the context for data requests and usage would improve the quality, timeliness, and participation of reporting. Some commenters stated that data reporting requirements and relevant interpretative guidance should be clearly communicated with adequate lead time so that facilities could develop, implement, and update workflows and procedures for collecting and reporting the necessary data, as well as any changes in the data they are required to report. A few commenters suggested that facilities would need this interpretive guidance with a minimum notice of 30 to 60 days to prepare data reporting workflows and procedures.

Response: We appreciate the feedback and suggestions provided regarding strategies to help support implementation and a smooth transition. As stated in the proposed rule, facilities will be notified of the specific reporting requirements (start date, data elements and definitions, frequency, etc.) and subsequent changes in guidance, such as a Quality, Safety, and Oversight (QSO) memorandum, consistent with the notification methods used previously for COVID–19-related reporting (87 FR 28620); (see QSO–21–03-Hospitals/CAHs at *https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0*). We will consider these comments when developing the interpretive guidance for this final rule.

B. Comments Focused on the Proposals for Continued COVID–19-Related Data Reporting

Comment: A few commenters stated that the proposal for continued COVID–19-related data was unclear, because the proposal indicated that hospitals and CAHs would report data in a standardized format specified by the Secretary. These commenters recommended that the rule clearly identify the systems by which hospitals and CAHs would be able to report data, to include HHS Protect.

Response: We agree that the rule does not identify specific systems for data reporting by hospitals and CAHs. Current regulations for COVID–19 reporting and reporting of acute respiratory illness, including seasonal influenza virus, influenza-like illness, and severe acute respiratory infection at § 482.42(e) and (f) (hospitals) and § 485.640(d) and (e) (CAHs) state that hospitals and CAHs must report information in a standardized format specified by the Secretary. We adopted that approach because it affords flexibility to adapt data reporting requirements in response to changing circumstances. In this rule, we maintain this regulatory language (in a standardized format as specified by the Secretary) thereby ensuring a sustained, flexible approach for continued COVID–19-related data reporting after the PHE ends. As indicated in the proposed rule, throughout the COVID–19 PHE, CMS notified hospitals and CAHs of the reporting requirements with QSO memorandums (for example, see QSO–21–03-Hospitals/CAHs at *https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0*.) We anticipate a similar model of notification for the continued COVID–19-related data reporting requirements finalized in this rule.

Comment: A few commenters stated that it was difficult to understand the purpose of continuing COVID–19-related reporting beyond the current PHE declaration. The commenters stated that the data is of questionable value given the current state of the pandemic. Some commenters recommended that the COVID–19-related reporting requirements end when the current PHE expires and restart in the event another PHE is declared.

Response: We acknowledge the concerns raised by commenters, however disagree that there is no value in continued COVID–19 reporting beyond the current PHE. Due to the unpredictable nature of the novel SARS-CoV–2 virus that causes COVID–19, we believe that continuing COVID–19-related data reporting is necessary to protect the health and safety of hospital and CAH patients as well as the communities in which the hospitals and CAHs are located. The COVID–19-related data reported by all hospitals and CAHs, have been, and continue to be, important in supporting surveillance of, and response to, COVID–19 and other respiratory illnesses. These data play an important role in evaluating spread of respiratory viruses and infections, including but not limited to COVID–19 and influenza. Retaining the data reporting requirements after the end of the current COVID–19 PHE is an important element of maintaining effective surveillance of this novel virus. Timely and actionable surveillance will enable CMS to continue to respond to facilities in need of additional technical support and oversight, should they experience increased cases or outbreaks of COVID–19 and/or influenza. Furthermore, we note that these requirements will sunset April 2024, unless the Secretary establishes an earlier end date, based upon the statutory authority in the Social Security Act that authorizes the Secretary to issue any regulations deemed necessary to protect the health and safety of patients receiving services in hospitals (section 1861(e)(9) of the Act) and CAHs (section 1820(e)(3) of the Act).

Comment: Some commenters stated that our proposal to continue COVID–19-related data reporting beyond the current PHE declaration was burdensome and labor intensive, especially for infection preventionists and nurses who have worked additional hours and taken on additional duties since the start of the COVID–19 pandemic in March 2020. These commenters indicated that the proposals would add to an already high level of stress among health care personnel, prompting individuals to leave their positions and thereby exacerbating staffing shortages. Some commenters offered suggestions for reducing the data categories required to mitigate concerns regarding burden, particularly those pertaining to suspected cases, staff vaccination, and staffing shortages as these have already been made optional or retired from

current reporting requirements under the PHE (available at *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf*). In addition, a few commenters suggested reducing or changing specific data elements for health care worker vaccination status, including but not limited to those elements for vaccine manufacturer and first and second doses in a series. Some commenters suggested that we reevaluate the data categories and reduce where necessary without identifying specific data categories to remove. Other commenters stated that the proposed data categories were reasonable and represented a balance between burden on facilities and patient health and safety considerations associated with COVID–19.

Response: We understand the burden concerns shared by commenters and appreciate the suggestions offered to mitigate those concerns. As noted previously, we believe this information collection and record is vital to ensure the health and safety of patients and the communities in which they live. However, we agree that in a post-PHE posture that certain COVID–19 specific data categories may not provide additional value to inform our surveillance and mitigation efforts. Therefore, as further discussed in this section, we have re-evaluated the proposed data elements in consideration of the feedback shared by commenters and the evolving state of the current PHE and are modifying our proposal to remove the following from the list of required data categories to report:

- Suspected COVID–19 infections among patients and staff—Although data pertaining to suspected cases were valuable throughout the COVID–19 PHE, particularly in instances when testing supplies were limited and cases were often identified based on clinical signs and symptoms, this information is less meaningful now that testing supplies are readily available to confirm the presence of infection. Thus, we do not believe suspected COVID–19 infection data would be necessary to collect from hospitals and CAHs once the PHE declaration ends, and therefore, we removed this data category.
- Confirmed COVID–19 and influenza infections among staff, confirmed co-morbid influenza and COVID–19 infections among staff, and COVID–19 and influenza deaths among staff—The data categories for staff (suspected infections among staff; confirmed COVID–19, influenza, and co-morbid infections among staff; COVID–19 and influenza deaths among staff) have not been among the information that hospitals and CAHs were required to report throughout the COVID–19 PHE. Hospitals and CAHs were required to report suspected, confirmed, and comorbid infections, as well as deaths, for patients only. Upon reflection, we do not believe collecting these data for staff from hospitals and CAHs post-PHE is necessary.

While beneficial during an active PHE and the specific circumstances of the COVID–19 PHE, we believe the data categories previously noted are not necessary to provide the most valuable information during a post-PHE state for continued monitoring, and as such we are removing these data categories to be responsive to commenter concerns regarding increased burden on facilities and staff, while also attempting to provide quality care for patients.

The data categories that we are finalizing in this rule that hospitals and CAHs will be required to report relevant to COVID–19, to the extent as determined by the Secretary, are as follows: Confirmed infections among patients; Total deaths among patients; Personal protective equipment and testing supplies; Ventilator use, capacity, and supplies; Total bed and intensive care unit bed census and capacity; Staffing shortages; Vaccine administration data of patients and staff; and Relevant therapeutic inventories or usage, or both. The data categories that we are finalizing in this rule that hospitals and CAHs will be required to report relevant to influenza, to the extent as determined by the Secretary, are as follows: Confirmed infections among patients; Total deaths among patients; and Confirmed co-morbid influenza and COVID–19 infections among patients. We believe these data will offer the most valuable information during a post-PHE state by continuing to capture critical data on COVID–19 for ongoing surveillance and to inform any potential action to protect patient health and safety. As previously discussed, these data will enable the federal government to monitor the ability of facilities to provide safe care for patients by determining the number of COVID–19 and influenza infections being treated by facilities; the quantity of resources available to facilities and the volume of resources they are using; and facilities' continued capacity to provide safe patient care. In addition, as done throughout the COVID–19 pandemic, local, state, and federal authorities will continue to use these data to identify possible resurgence in cases and outbreaks, for resource allocation purposes, and to update guidance pertaining to the safe provision of patient care.

As indicated in the proposal, we do not expect continued daily reporting for COVID–19 or influenza outside of a declared PHE. Moreover, the rule allows for the scope of data categories and frequency of data collection and reporting to be reduced and limited, as determined by the Secretary, responsive to evolving clinical and epidemiology circumstances. This approach to reducing the proposed set of required data categories will provide a path towards winding down the overall reporting of COVID–19-related data between the end of the current PHE and April 2024, when these requirements will sunset. These requirements will not be implemented and enforced until the current COVID–19 PHE declaration concludes, and CMS will issue guidance indicating such a transition. As discussed previously, we expect the method of notification to follow a model similar to that which we used to inform regulated entities at the beginning of the COVID–19 PHE (see QSO–21–03-Hospitals/CAHs at *https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0*).

C. Comments Pertaining to the Proposals for Data Reporting in the Event of a Future PHE Declaration

Comment: In the proposed rule, we solicited comment on the potential that long-term data collection in the event of a future PHE may duplicate elements already reported elsewhere and on the feasibility of such a requirement. Many commenters acknowledged the hard work of the hospital system during the COVID–19 PHE and the many efforts taken by facilities to quickly adapt and respond to both the demands of the PHE and the requirements to report critical data for monitoring and surveillance. When considering the feasibility of maintaining these efforts long-term, a few commenters questioned the appropriateness of requiring its collection as a CoP (noting that many hospitals provided such data voluntarily prior to mandating its collection), especially within the CoPs for infection prevention and control and antibiotic stewardship. Specifically, these commenters indicated that the COVID–19 data do not directly or indirectly reflect a facility's infection control policies or practices, but rather, are descriptive of public health information (such as, infection rate, bed capacity, supplies, etc.). With regard to duplication, some commenters raised concerns about accessibility and the flow of reported information across various government entities and response partners. Many noted that, throughout the COVID–19 PHE,

hospitals have been required to report similar (but not necessarily standardized) data elements to multiple agencies (federal, state, local) and through multiple platforms. Likewise, commenters also reiterated that various reporting requirements already exist such as requirements to report quality measures and shared concerns that the new requirements proposed would perpetuate, if not exacerbate, reporting redundancies that tax already limited facility and staff time and resources—particularly if state and local public health and emergency management agencies do not have timely or complete access to data reported through federal systems. Nearly all of these commenters called for CMS and other HHS agencies to work closely with facilities, as well as state and local agencies, to align and streamline future reporting requirements.

Response: We appreciate this informative feedback regarding the challenges and often redundant efforts associated with current reporting. As noted in the proposed rule, CMS does not intend to supplant or duplicate existing state and local requirements and mechanisms for reporting of public health and disease surveillance data (87 FR 28622). We believe that the reporting requirements proposed for health care facilities in these CoPs are distinct from and serve a different purpose than case surveillance of notifiable diseases and conditions that is conducted by state and local health departments. State and local authorities define their own reporting requirements and data definitions, but differences among these data neither enable comparisons across states and local jurisdictions nor provide a national perspective. Moreover, HHS does not have easy access to the data reported to state and local authorities; these authorities are not required to report the data to the federal government, and, unless such authorities are also directly providing health services, CMS has no authority to require state and local authorities to collect certain data, standardize the data collected, and report such data to the federal government. However, as discussed previously in this rule, during the COVID–19 PHE, HHS worked with states and other jurisdictions to ensure they had access to the data reported by hospitals and CAHs directly to the federal government, and several states submitted data to the federal government on behalf of hospitals and CAHs within their jurisdictions. HHS will continue to partner with state and local jurisdictions, health care facilities, and stakeholders to coordinate data collection, sharing, and accessibility in a streamlined fashion that satisfies the needs of all stakeholders while reducing duplicative reporting requirements, to the extent possible. Also as previously discussed, data collected and reported by hospitals and CAHs during the COVID–19 PHE enabled the federal government to monitor the ability of facilities to provide safe care to patients, and these date were used by local, state, and federal government agencies to allocate resources (such as PPE, staff, strike teams, funding) to hospitals and to update guidance on the provision of care, which was particularly important during periods of staffing and PPE scarcity and limited capacity. Therefore, we continue to see the value in creating long-term opportunities to activate the collection of this data and the need for increased preparedness across the health care system in the event of a future PHE. Lessons learned from the COVID–19 PHE have also highlighted the need for and importance of community engagement and collaboration amongst hospitals and CAHs, but also across provider types.

Throughout the COVID–19 pandemic, it has been imperative for facilities to have the ability to both assess and communicate their needs and to monitor their ability to continue to provide safe care. While we can appreciate the concerns shared by commenters regarding the burden and appropriateness of including a requirement for surveillance reporting as a long-term CoP in a facility's infection control and prevention standards, we disagree that such reporting is not appropriate for the CoPs in an effort to protect patient health and safety. However, we agree that additional consideration is necessary to fully establish a long-term solution for ensuring the preparedness of the healthcare system in the event of another PHE. Therefore, we are withdrawing our proposal to require future infectious disease reporting in the event of a declared PHE. We agree that continued collaboration across government partners and engagement with interested parties to standardize and streamline reporting efforts would be beneficial. We also echo commenters encouragement to continue efforts to further enhance the infrastructure used to support the submission of data for the long-term in hopes of mitigating many of the burden concerns raised by comments. We appreciate the commenters who have acknowledged the ongoing efforts by facilities to meet the current reporting requirements and the willingness of many hospitals to report the information voluntarily. While CMS considers a longer-term solution for ensuring overall preparedness as previously noted, it is our expectation that hospitals and CAHs will continue increasing their readiness and will be prepared to report data in the event of a future declared PHE.

Comment: We received a mixed response to our proposal to require facilities to report person-level data during a pandemic. Commenters who supported the proposal noted that person-level data would provide information about how different groups are affected by an infectious disease thereby supporting efforts focused on advancing health equity and suggested this data should include socioeconomic status. Commenters who disagreed noted concerns related to burden and indicated that such reporting would be unreasonable, particularly for larger facilities or those facilities lacking automated processes to collect and report such data. These commenters also questioned the use of and need for person-level data. Other commenters acknowledged our efforts to limit any directly or potentially individually identifiable person-level data, but noted the that local health departments currently use information such as name, date of birth, and patient addresses to link case and exposure data to identify clusters and inform infection prevention and control efforts by local jurisdictions.

Response: We thank commenters for their feedback. We believe that person-level data elements, such as race, ethnicity, age, sex residential county and zip code, and relevant comorbidities for affected patients, will help to inform response management and address health equity issues. In the absence of these data, it is challenging to take actions to reduce disparities in disease incidence and severity, access, and effectiveness of relevant preventive and therapeutic services (for example, vaccines) among vulnerable or otherwise marginalized populations. As noted in the proposed rule, the lack of individual data elements was an important gap raised during the COVID–19 PHE and we are seeking ways to increase our ability to follow patients through the health care system to provide actionable information on outcomes and health care facility capacities. We will consider all of the feedback received as we continue to explore issues of if and when person-level data may be warranted in the context of future PHE reporting requirements.

Comment: Many commenters supported our proposal to require facilities to report the required data to

the NHSN or some other CDC-supported surveillance system. Commenters acknowledged the CDC's NHSN as a leader for data collection and reporting in health care settings and supported our goal of promoting a standardized and streamlined framework for data reporting. However, while supporting the use of NHSN commenters emphasized that its usage must complement, not replace, existing data collection efforts that provide awareness and inform health care practices, especially those at the local level. Commenters noted that local health departments are increasingly called to facilitate coordination between health care facilities, provide leadership in response efforts, and often leverage their jurisdictional data to establish trends for their jurisdiction, and target stewardship and infection prevention and control initiatives. These commenters shared concerns regarding the likelihood that critical data would continue to be reported to both NHSN and any local surveillance systems given the resource burden that would be placed on providers. Specifically, commenters noted systems such as those used for case reporting, laboratory data, and vaccination registries.

Response: We appreciate the feedback and the additional comments noted previously regarding additional reporting streams and data collection efforts. In the proposed rule, we noted that we proposed reporting the CDC's NHSN because it is a vendor-neutral, federally owned system and as such provides ready access to data to state and many local public health agencies and can accept data submitted by outside vendors contracted either by hospitals, jurisdictions, or other Federal entities to submit data on behalf of providers (87 FR 28622). Additionally, as previously noted in the proposed rule, through resources provided by the American Rescue Plan Act and its Data Modernization Initiative, CDC is investing in increasing the automation capabilities of surveillance systems, like NHSN, and its ability to connect with other data submission techniques, vendors, and systems to further automate data collection, reduce provider burden, and increase data accessibility for stakeholders. In the proposed rule, CMS also noted the existing requirement for eligible hospitals and CAHs participating in the Promoting Interoperability Program to report four of the six of the measures associated with the Public Health and Clinical Data Exchange Objective (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting), and that to take advance of other reporting streams, CMS would consider other CDC-supported surveillance systems, as determined by the Secretary, for data reporting to allow for flexibility in the designation of future systems that are most capable of meeting these needs. We will consider all of these comments as we continue to seek opportunities to work with interested parties to explore the most effective approaches for data reporting that informs the success of our response efforts, incentivizes and encourages preparedness among providers in the event of a future PHE, and ensures health and safety for patients and communities served by providers.

Final Rule Action: After consideration of the public comments, we are finalizing our proposal with the following changes—

1. We are modifying our proposal at §§ 482.42(e) and (f) for hospitals and §§ 485.640(d) and (e) for CAHs, to decrease the scope of data categories required for continued COVID–19 and seasonal influenza reporting.

2. We are withdrawing our proposal to add new paragraphs at 482.42(g) (hospitals) and 485.640(f) (CAHs), to establish reporting requirements for an infectious disease in the event of a PHE declaration. CMS believes that additional consideration is necessary to establish a longer-term solution for data collection and reporting that ensures the ongoing preparedness of the entire health care system in the event of another PHE involving an infectious disease or a PHE resulting from natural or human-made factors. We also believe that continued collaboration among government and interested parties would be beneficial to standardize and streamline data reporting to the extent possible thereby reducing burden on facilities, particularly during emergencies when resources are stretched and patient care-related work demands are elevated. As previously discussed, while CMS considers a longer-term solution for ensuring overall preparedness in the event of future emergencies, it is our expectation that hospitals and CAHs will continue assessing and improving their readiness to report data in the event of a future declared PHE, consistent with their existing requirements for emergency preparedness.

C. Public Comments Requested on IPPS and OPPS Payment Adjustments for Wholly Domestically Made NIOSH-Approved Surgical N95 Respirators

In the FY 2023 IPPS/LTCH PPS proposed rule, we requested public comments on potential IPPS and OPPS payment adjustments for wholly domestically made National Institute for Occupational Safety & Health (NIOSH)-approved surgical N95 respirators (87 FR 28622 through 28625). Given the importance of NIOSH-approved surgical N95 respirators in protecting hospital personnel and beneficiaries from the SARS–CoV–2 virus and future respiratory pandemic illnesses, we indicated we were considering whether it might be appropriate to provide payment adjustments to hospitals to recognize the additional resource costs they incur to acquire NIOSH-approved surgical N95 respirators that are wholly domestically made. We stated that NIOSH-approved surgical N95 respirators, which faced severe shortage at the onset of the COVID–19 pandemic, are essential for the protection of patients and hospital personnel that interface with patients. We indicated that procurement of NIOSH-approved surgical N95 respirators that are wholly domestically made, while critical to pandemic preparedness and protecting health care workers and patients, can result in additional resource costs for hospitals.

We stated we were interested in feedback and comments on the appropriateness of payment adjustments that would account for these additional resource costs. We stated that we believed such payment adjustments could help achieve a strategic policy goal, namely, sustaining a level of supply resilience for NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency. We stated we were considering such payment adjustments for 2023 and potentially subsequent years.

We received many comments that were helpful in developing the payment adjustment that we proposed in the CY 2023 OPPS/ASC proposed rule. For instance, many commenters were supportive of a payment adjustment, acknowledging the importance of surgical N95 respirators in keeping health care workers and patients safe and attesting to the difficulties of procuring surgical N95 respirators during the height of the COVID–19 pandemic. The majority of commenters supported an approach of CMS making biweekly interim lump-sum payments

that would be reconciled at cost report settlement, although some commenters preferred a claims-based approach. Many commenters urged CMS to minimize the administrative burden on hospitals in the development of any N95 payment policy. We also acknowledge the comments of MedPAC and others stating that Medicare payment policy is not the most appropriate mechanism to support domestic manufacturing of medical supplies.

In the CY 2023 OPPS/ASC proposed rule, we proposed to make a payment adjustment under the OPPS and IPPS for the additional resource costs of domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. We refer the reader to the CY 2023 OPPS/ASC proposed rule for the complete discussion on this proposal.

XI. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2022 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2023 are addressed in Appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at *https://www.medpac.gov*.

XII. Other Required Information

A. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We listed the data files available in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28625 through 28627).

Commenters interested in discussing any data files used in construction of this final rule should contact Michael Treitel at (410) 786–4552.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the FY 2023 IPPS/LTCH PPS proposed rule, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for the Hospital Wage Index for Acute Care Hospitals

Section III.E.1. of the preamble of this final rule, use of 2019 Medicare wage index occupational mix survey for the FY 2023 wage index, references the information collection request currently approved under 0938–0907. There were no proposed changes to the currently approved information collection request associated with this rulemaking; however, we note that the information collection expires October 31, 2022. An extension of the information collection request is currently being developed. The public will have an opportunity to review and submit comments regarding the extension of this PRA package through a public notice and comment period separate from this rulemaking.

Section III.I.2.a. of the preamble of this final rule, FY 2023 Reclassification Application Requirements and Approvals, references the information collection request 0938–0573 which expired on January 31, 2021. A reinstatement of the information collection request is currently being developed. The public will have an opportunity to review and submit comments regarding the reinstatement of this PRA package through a public notice and comment period separate from this rulemaking.

We did not receive comments regarding the ICRs for the hospital wage index for acute care hospitals.

3. ICRs for Payments for Low-Volume Hospitals

As discussed in section V.C. of this final rule, in accordance with section 1886(d)(12) of the Act, beginning with FY 2023, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and subsequent legislation. Therefore, effective for FY 2023 and subsequent years, under current policy at § 412.101(b), in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges during the fiscal year. In that section we also discuss the process for requesting and obtaining the low-volume hospital payment adjustment under § 412.101. Specifically, a hospital makes a written request to its MAC that contains sufficient documentation to establish that the hospital meets the applicable statutory mileage and discharge criteria. While this information collection requirement would normally be subject to the PRA, we believe in this instance it is exempt. Based on historical data, we estimated there are fewer than 5 hospitals among all subsection (d) hospitals that will meet the applicable mileage and discharge criteria for FY 2023. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(c)(4), the requirement will be exempt as it affects less than 10 entities in a 12-month period.

We did not receive comments regarding the ICRs for payments for low-volume hospitals.

4. ICRs Relating to the Hospital Readmissions Reduction Program

In section V.H of the preamble of this final rule, we discuss requirements for the Hospital Readmissions Reduction Program. In this rule, we are not removing or adopting any new measures into the Hospital Readmissions Reduction Program for FY 2023. All six of the current Hospital Readmissions Reduction Program's measures are claims-based measures. We believe that continuing to use these claims-based measures would not create or reduce any information collection burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to

the Medicare program for payment purposes.

5. ICRs for the Hospital Value—Based Purchasing (VBP) Program

In section V.I. of the preamble of this final rule, we discuss new requirements we are finalizing for the Hospital VBP Program. Specifically, in this final rule, with respect to quality measures, we are finalizing our proposals to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and the five Healthcare—Associated Infection (HAI) measures for the FY 2023 program year. We are also finalizing our proposal to continue requiring hospitals to report data for all measures, including measures we are suppressing for FY 2023. Because the FY 2023 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare FFS claims data that hospitals are already submitting to CMS for payment purposes, we do not anticipate any change in burden associated with this final rule.

6. ICRs Relating to the Hospital-Acquired Condition (HAC) Reduction Program

In this final rule, we are not removing any measures, adopting any new measures into the HAC Reduction Program, or updating our validation procedures.[1162] The HAC Reduction Program has previously adopted six measures: the CMS PSI 90 measure and five CDC NHSN HAI measures. We are not finalizing our proposal to not calculate measure results for PSI 90 and thus will be calculating measure results for the FY 2023 HAC Reduction program. We do not believe that the claims-based CMS PSI 90 measure in the HAC Reduction Program creates additional burden for hospitals because the measure is calculated using the Medicare FFS claims that hospitals have submitted to the Medicare program for payment purposes. Accordingly, we do not believe that our finalized policy in sections V.J.3.c.(1). to increase the minimum volume threshold for the CMS PSI 90 measure changes any information collection burden for hospitals.

We note the burden associated with collecting and submitting data for the HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA bacteremia, and CDI) via the CDC's NHSN system is captured under a separate OMB control number, 0920–0666 (expiration January 1, 2025). As discussed in sections V.J.2.b.(2). and V.J.2.b.(3). of the preamble of this final rule, we are suppressing the five NHSN measures from the FY 2023 HAC Reduction Program. We are also suppressing CY 2021 CDC NHSN HAI data from the FY 2024 program year. Because hospitals would continue to report data for the HAI measures, this policy does not change information collection burden for hospitals as accounted for under CDC's OMB control number 0920–1066.

In section V.J.7. of the preamble of this final rule, we clarify the removal of the No Mapped Locations (NML) policy beginning in FY 2023. Hospitals will be required to appropriately submit data to the NHSN or, if hospitals do not have the applicable locations for the CLABSI and CAUTI measures, the hospital must submit an IPPS Measure Exception Form to be exempt from CLABSI and CAUTI reporting for CMS programs. The burden for all hospitals to submit data to the NHSN is already accounted for under OMB control number 0920–0666, therefore there is no increase in burden for hospitals which submit data as a result of this clarification. In addition, the burden associated with completion of forms (including the IPPS Measure Exception Form) is already accounted for under OMB control number 0938–1022 (expiration date December 31, 2022), therefore there is no increase in burden for hospitals which elect to submit this form as a result of this clarification. This clarification does not necessitate substantive changes to the IPPS Measure Exception Form, therefore any change in burden is negligible and our currently approved burden estimates under OMB control number 0938–1022 are conservative enough to accommodate the change. Revisions to the IPPS Measure Exception Form, will be submitted for approval under OMB control number 0938–1022.

We did not receive comments regarding the ICRs for the HAC Reduction Program.

7. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. OMB has currently approved 1,572,810 hours of burden and approximately $65 million under OMB control number 0938–1022 (expiration date December 31, 2022), accounting for information collection burden experienced by approximately 3,300 IPPS hospitals and 1,100 non-IPPS hospitals for the FY 2024 payment determination. In the proposed rule (87 FR 28627 through 28635) and this final rule, we describe the burden changes regarding collection of information under OMB control number 0938–1022 (expiration date December 31, 2022) for IPPS hospitals.

For more detailed information on our finalized policies for the Hospital IQR Program, we refer readers to section IX.E. of the preamble of this final rule. We are adopting four measures that we expect to affect our collection of information burden estimates: (1) The Hospital Commitment to Health Equity structural measure, beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years; (2) the Screening for Social Drivers of Health measure, beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) the Screen Positive Rate for Social Drivers of Health measure, beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; and (4) the Hospital-level THA/TKA PRO–PM, beginning with voluntary reporting across two periods, followed by mandatory reporting of the measure for the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination. We are also modifying our eCQM reporting and submission requirements which will increase the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination, which will additionally affect our collection of information burden. The estimated collection of burden associated with our finalized proposals is discussed in this section of this final rule.

We are also finalizing policies which will not affect the information collection burden associated with the Hospital IQR Program. As discussed in section IX.E. of the preamble of this final rule, we are adopting four eCQMs: (1) Cesarean Birth electronic clinical quality measure (eCQM), with inclusion in the eCQM measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, followed by mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment

[1162] Burden associated with the validation procedures in the HAC Reduction Program are accounted for under OMB Control Number 0938–1352.

determination; (2) Severe Obstetric Complications eCQM, with inclusion in the eCQM measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, followed by mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) Hospital-Harm—Opioid-Related Adverse Events eCQM, beginning with inclusion in the eCQM measure set in the CY 2024 reporting period/FY 2026 payment determination; and (4) Global Malnutrition Composite Score eCQM, beginning with inclusion in the eCQM measure set in the CY 2024 reporting period/FY 2026 payment determination. We are also adopting two claims-based measures beginning with the FY 2024 payment determination: (1) MSPB Hospital; and (2) the Hospital-Level RSCR Following Elective Primary THA/TKA. We are refining two current Hospital IQR Program claims-based measures beginning with the FY 2024 payment determination: (1) Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA/TKA; and (2) The Acute Myocardial Infarction (AMI) Excess Days in Acute Care (EDAC). Lastly, we are: (1) Establishing a hospital designation related to patient care to be publicly-reported on a public-facing website beginning in Fall 2023; (2) modifying our case threshold exemptions and zero denominator declaration policies for hybrid measures as we believe they are not applicable for this measure type beginning with the FY 2026 payment determination; and (3) modifying our eCQM validation policy to increase the reporting of medical requests from 75 percent of records to 100 percent of records, beginning with the validation of CY 2022 eCQM data affecting the FY 2025 payment determination.

The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $21.20 per hour for a medical records and health information technician professional.[1163] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($21.20 × 2 = $42.40) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of $42.40 per hour throughout the discussion in this section of this rule for the Hospital IQR Program.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45507), our burden estimates were based on an assumption of approximately 3,300 IPPS hospitals. For this final rule, we are updating our assumption to 3,150 IPPS hospitals based on recent data from the FY 2022 Hospital IQR Program payment determination which reflects a closer approximation of the total number of hospitals reporting data to the Hospital IQR Program.

b. Information Collection Burden Estimate for the Hospital Commitment to Health Equity Structural Measure Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

In section IX.E.5.a. of the preamble of this final rule, we are finalizing adoption of the Hospital Commitment to Health Equity structural measure beginning with the CY 2023 reporting period/FY 2025 payment determination. Hospitals will report data through the Hospital Quality Reporting (HQR) System.

Hospitals will submit the response on an annual basis during the submission period. We estimate the information collection burden associated with this structural measure to be, on average across all 3,150 IPPS hospitals, no more than 10 minutes per hospital per year, as it involves attesting to as many as five questions one time per year for a given reporting period. While we understand some hospitals may require more than 10 minutes to research the information needed to respond, we believe that the majority of hospitals will have the information readily available to respond to the questions listed in section IX.E.5.a. of the preamble of this final rule and will require less than 10 minutes. In addition, we believe that many hospitals will be able to submit similar responses in future years, thereby reducing the actual time to respond in subsequent reporting periods. Using the estimate of 10 minutes (or 0.167 hours) per hospital per year, and the updated wage estimate as described previously, we estimate that this policy will result in a total annual burden increase of 525 hours across all participating IPPS hospitals (0.167 hours × 3,150 IPPS hospitals) at a cost of $22,260 (525 hours × $42.40). With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this final rule).

c. Information Collection Burden Estimate for the Screening for Social Drivers of Health Measure Beginning With Voluntary Reporting in the CY 2023 Reporting Period and Mandatory Reporting in the CY 2024 Reporting Period/FY 2026 Payment Determination

In section IX.E.5.b.(1). of the preamble of this final rule, we are adopting the Screening for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination. Hospitals will report data through the HQR System.

As discussed in the preamble of this final rule, hospitals will be able to collect data and report the measure via multiple methods. We believe that most hospitals will likely collect data through a screening tool incorporated into their electronic health record (EHR) or other patient intake process.

We believe the Outcome and Assessment Information Set (OASIS), which is currently used in the Home Health Quality Reporting Program, is a reasonable comparison for estimating the information collection burden for the Screening for Social Drivers of Health measure due to analogous assessment of patient-level need. The OASIS is a core standard assessment data set home health agencies integrate into their own patient-specific, comprehensive assessment to identify each patient's need for home care that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For OASIS, the currently approved information collection burden under OMB 0938–1279 (expiration date November 30, 2024) is estimated to be 0.3 minutes per data element (18 seconds). For the five HRSN domains screened for by the Social Drivers of Health measure under the Hospital IQR Program, we estimate a total of 2 minutes (0.033 hours) per patient to conduct this screening. The most recent data from the Bureau of Labor Statistics reflects an Average Hourly Earnings of $31.31.[1164] Based on information collected by the American Hospital Association,[1165] we estimate

[1163] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records and Health Information Technicians. Accessed on January 13, 2022. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[1164] U.S. Bureau of Labor Statistics. Economy at a Glance, Average Hourly Earnings. Accessed on January 24, 2022; available at: *https://www.bls.gov/eag/eag.us.htm.*

[1165] *https://www.aha.org/system/files/media/file/2020/01/2020-aha-hospital-fast-facts-new-Jan-2020.pdf.*

approximately 21,000,000 patients (34,251,159 total admissions in U.S. community hospitals × 3,150 IPPS hospitals ÷ 5,198 total U.S. community hospitals) will be screened annually across all participating IPPS hospitals. For the purposes of calculating burden, we estimate that during the voluntary period, 50 percent of hospitals will survey 50 percent of patients. We estimate during the mandatory period, hospitals would submit for 100 percent of patients. For the CY 2023 voluntary reporting period, we estimate a total burden of 175,000 hours (21,000,000 respondents × 50 percent of patients × 50 hospitals of hospitals × 0.033 hours) at a cost of $5,479,250 (175,000 hours × $31.31) across all participating IPPS hospitals. For the CY 2024 reporting period and subsequent years, we estimate a total annual burden of 700,000 hours (21,000,000 respondents × 0.033 hours) at a cost of $21,917,000 (700,000 hours × $31.31) across all participating IPPS hospitals.

Measure data will be submitted via the HQR System annually. Similar to the currently approved data submission and reporting burden estimate for eCQMs in the Hospital IQR Program and web-based measures for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program (OMB control number 0938–1270; expiration date July 31, 2024) reported via the HQR System, we estimate a burden of 10 minutes per hospital response to transmit the measure data. Therefore, we estimate that each participating facility will spend 10 minutes (0.1667 hours) annually to collect and submit the data via this portal. For the purposes of calculating burden, we estimate that during the voluntary period, 50 percent of hospitals will submit data. For the CY 2023 voluntary reporting period, we estimate a total burden of 263 hours (0.1667 hours × 3,150 hospitals × 50 percent of hospitals) at a cost of $11,151 (263 hours × $42.40) across all participating IPPS hospitals. For the CY 2024 reporting period and subsequent years, we estimate a total annual burden for all participating IPPS hospitals of 525 hours (0.1667 hours × 3,150 hospitals) at a cost of $22,260 (525 hours × $42.40).

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this final rule).

d. Information Collection Burden Estimate for the Screen Positive Rate for Social Drivers of Health Process Measure Beginning With Voluntary Reporting in the CY 2023 Reporting Period and Mandatory Reporting Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section IX.E.5.b.(2). of the preamble of this final rule, we are adopting the Screen Positive Rate for Social Drivers of Health measure beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination. Hospitals will report data through the HQR System. For this measure, hospitals will be required to report on an annual basis the number of patients who screen positive for one or more of the five domains (reported as five separate rates) divided by the total number of patients screened.

We previously included the burden associated with screening patients in our discussion of the Screening for Social Drivers of Health measure. For this measure, we estimate only the additional burden for a hospital reporting via the HQR System since patients would not need to provide any additional information for this measure. We estimate that each participating facility will spend 10 minutes (0.1667 hours) annually to collect and submit the data. For the purposes of calculating burden, we estimate that during the voluntary period, 50 percent of hospitals would submit data. For the CY 2023 voluntary reporting period, we estimate a total burden of 263 hours (0.1667 hours × 3,150 hospitals × 50 percent of hospitals) at a cost of $11,130 (263 hours × $42.40) across all participating IPPS hospitals. For the CY 2024 reporting period and subsequent years, we estimate a total annual burden estimate for all IPPS hospitals of 525 hours (0.1667 hours × 3,150 hospitals) at a cost of $22,260 (525 hours × $42.40).

e. Information Collection Burden Estimate for the Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Beginning With Two Voluntary Reporting Periods Followed by Mandatory Reporting for Eligible Elective Procedures Occurring July 1, 2025 Through June 30, 2026, Impacting the FY 2028 Payment Determination, and for Subsequent Years

In section IX.E.5.g. of the preamble of this final rule, we are adopting the THA/TKA PRO–PM beginning with voluntary reporting across two periods (July 1, 2023 through June 30, 2024 and July 1, 2024 through June 30, 2025), followed by mandatory reporting of the measure beginning with the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination.

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. We estimate no additional burden associated with claims data, Medicare enrollment and beneficiary data, and U.S. Census Bureau survey data as these data are already collected via other mechanisms.

Many hospitals have already incorporated patient-reported outcome (PRO) data collection into their workflows. While we are not requiring how hospitals collect data, hospitals new to collecting PRO data have multiple options for when and how they would collect this data so they can best determine the mode and timing of collection that works best for their patient population. The possible patient touchpoints for pre-operative PRO data collection include the doctor's office, pre-surgical steps such as education classes, or medical evaluations that can occur in an office or at the hospital. The modes of PRO data collection can include completion of the pre-operative surveys using electronic devices (such as an iPad or tablet), pen and paper, mail, phone call, or through the patient's portal. Post-operative PRO data collection modes are similar to pre-operative modes. The possible patient touchpoints for post-operative data collection can occur before the follow-up appointment, at the doctor's office, or after the follow-up appointment. The potential modes of PRO data collection for post-operative data are the same as for pre-operative data. If the patient does not or cannot attend a follow-up appointment, the modes of collection can include completion of the post-operative survey using email, mail, phone, or through the patient portal. Use of multiple modes will increase response rates as it allows for different patient preferences.

For the THA/TKA PRO–PM data, hospitals will be able to submit data during two voluntary periods, followed by mandatory reporting for eligible elective procedures occurring July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination and for subsequent years. Hospitals will need to submit data twice (pre-operative data and post-operative data). For the

purposes of calculating burden, we estimate that during the voluntary periods, 50 percent of hospitals that perform at least one THA/TKA procedure would submit data, and will do so for 50 percent of THA/TKA patients. We estimate during the mandatory period, hospitals will submit for 100 percent of patients. While we are requiring hospitals to submit, at minimum, 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data, we are conservative in our estimate for the mandatory period in case hospitals exceed this threshold.

Under OMB control number 0938–0981 (expiration date September 30, 2024), the currently approved burden per respondent to complete the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure is 7.25 minutes (0.120833 hours). We estimate that the time to complete both the preoperative and post-operative surveys is analogous to completing the HCAHPS Survey once. The most recent data from the Bureau of Labor Statistics reflects an Average Hourly Earnings of $31.31.[1166] For burden estimating purposes, we assume that most hospitals will likely undertake PRO data collection through a screening tool incorporated into their EHR or other patient intake process. We estimate that approximately 330,000 THA/TKA procedures occur in the inpatient setting each year, and that many patients could complete both the pre-operative and postoperative questionnaires, although from our experience with using this measure in the Comprehensive Joint Replacement model, we are also aware that not all patients who complete the pre-operative questionnaire would complete the post-operative questionnaire. Due to the performance period for the first voluntary reporting period being 6 months, we assume 41,250 patients will complete the survey (165,000 patients × 0.50 × 0.50 of hospitals) for a total of 4,984 hours annually (41,250 respondents × 0.120833 hours) at a cost of $156,049 (4,984 hours × $31.31) across all IPPS hospitals. For the second voluntary reporting periods, we assume 82,500 patients will complete the survey (330,000 patients × 0.50 × 0.50 hospitals) for a total of 9,969 hours annually (82,500 respondents × 0.120833 hours) at a cost of $312,122 (9,969 hours × $31.31) across all IPPS hospitals. Beginning with mandatory reporting for the FY 2028 payment determination, we estimate a total of 39,875 hours (330,000 patients × 0.120833 hours) at a cost of $1,248,486 (39,875 hours × $31.31) across all IPPS hospitals.

For the data submission, which will be reported via the HQR System, we estimate a burden of 10 minutes per response. For each of the two voluntary reporting periods, we estimate that each hospital will spend 20 minutes (0.33 hours) annually (10 minutes × 2 surveys) to collect and submit the data via this tool. We estimate a resulting burden for all participating IPPS hospitals of 525 hours (0.33 hours × 3,150 hospitals × 50 percent) at a cost of $22,260 (525 hours × $42.40). Beginning with mandatory reporting for the FY 2028 payment determination, we estimate a total of 1,050 hours (0.33 hours × 3,150 hospitals) at a cost of $44,520 (1,050 hours × $42.40).

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this final rule).

f. Information Collection Burden Estimate for the Modification of the eCQM Reporting and Submission Requirements Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section IX.E.10.e. of the preamble of this final rule, we are modifying our eCQM reporting and submission requirements whereby we are increasing the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination.

We previously finalized in the FY 2020 IPPS/LTCH PPS final rule that, for the CY 2021 reporting period/FY 2023 payment determination, hospitals are required to submit data for four self-selected eCQMs each year (84 FR 42503). Additionally, for the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to submit data for three self-selected eCQMs and the Safe Use of Opioids-Concurrent Prescribing eCQM for a total of four eCQMs (84 FR 42505). We also finalized in the FY 2021 IPPS/LTCH PPS final rule to require hospitals to submit four quarters of eCQM data beginning in the CY 2023 reporting period/FY 2025 payment determination (85 FR 59008 through 59009). We continue to estimate the information collection burden associated with the eCQM reporting and submission requirements to be 10 minutes per measure per quarter. For the increase in submission from four to six eCQMs, we estimate a total of 20 minutes or 0.33 hours (10 minutes × 2 eCQMs) per hospital per quarter. We estimate a total burden increase of 1,050 hours across all participating IPPS hospitals (0.33 hour × 3,150 IPPS hospitals) for each quarter of eCQM data or 4,200 hours annually (1,050 hours × 4 quarters) at a cost of $178,080 (4,200 hours × $42.40).

g. Information Collection Burden Estimate for the Adoption of Four eCQMs: Two Perinatal eCQMs Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination; One Opioid-Related Hospital-Harm eCQM and One Malnutrition eCQM Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In sections IX.E.5.c. and IX.E.5.d. of the preamble of this final rule, we are adopting two perinatal eCQMs—Cesarean Birth and Severe Obstetric Complications—beginning with the CY 2023 reporting period/FY 2025 payment determination, followed by mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. Also, in sections IX.E.5.e. and IX.E.5.f. of the preamble of this final rule, we are adopting the Hospital-Harm—Opioid-Related Adverse Events eCQM and the Global Malnutrition Composite Score eCQM, respectively, beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

The addition of these four eCQMs do not affect the information collection burden of submitting eCQMs under the Hospital IQR Program. Current Hospital IQR Program policy requires hospitals to select four eCQMs from the eCQM measure set on which to report (84 FR 42503 through 4250). In other words, although these new eCQMs are being added to the eCQM measure set, hospitals are not required to report more than a total of six eCQMs, as finalized in section IX.E.10.e. of the preamble of this final rule. In the previous section XII.B.4.f. (of the Collection of Information section of this final rule), we account for the burden of reporting six eCQMs.

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this final rule).

[1166] U.S. Bureau of Labor Statistics. Economy at a Glance, Average Hourly Earnings. Accessed on January 24, 2022; available at: *https://www.bls.gov/eag/eag.us.htm.*

h. Information Collection Burden Estimate for the Adoption or Refinement of Four Claims-Based Measures

In sections IX.E.5.h., IX.E.5.i., IX.E.6.a., and IX.E.6.b. of the preamble of this final rule, we are adopting two claims-based measures—MSPB Hospital and Hospital-Level RSCR Following Elective Primary THA/TKA—and refining two claims-based measures currently in the Hospital IQR Program measure set—Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA/TKA and AMI EDAC. We are adopting the Hospital MSPB measure and the Hospital-Level RSCR Following Elective Primary THA/TKA beginning with the FY 2024 payment determination and are refining the other two measures beginning with the FY 2024 payment determination and for subsequent years. Because these measures are calculated using data that are already reported to the Medicare program for payment purposes, adopting and refining these measures does not result in a change to the burden estimates provided in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45507 through 45512).

i. Information Collection Burden Estimate for Addition of the Publicly-Reported Hospital Designation To Capture Hospital Commitment to the Quality and Safety of Maternal Health Beginning Fall 2023

In section IX.E.8. of the preamble of this final rule, we are establishing the publicly-reported hospital designation to capture hospital commitment to the quality and safety of maternity care on a CMS website, for hospitals who qualify for the designation, beginning in Fall 2023. In the FY 2022 IPPS/LTCH PPS final rule, we finalized adoption of the Maternal Morbidity Structural measure (86 FR 45365) and accounted for that burden under OMB control number 0938–1022 (expiration date December 31, 2022). We expect that our policy will not yield a change in burden as it does not require any additional information collection nor affect the requirements for data submission for hospitals.

j. Information Collection Burden Estimate for the Modification of the Case Threshold Exemptions and Zero Denominator Declaration Policies for Hybrid Measures Beginning With the FY 2026 Payment Determination

In section IX.E.10.f.(4). of the preamble of this final rule, we are modifying our case threshold exemptions and zero denominator declaration policies for hybrid measures as we believe they are not applicable for those measure types, beginning with the FY 2026 payment determination and for subsequent years.

In the FY 2020 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (Hybrid HWR) (84 FR 42505 through 42508) and in the FY 2022 IPPS/LTCH PPS final rule, we finalized the Hybrid Hospital-Wide Mortality Measure with Claims and Electronic Health Record Data (Hybrid HWM) (86 FR 45508). For each hybrid measure, all IPPS hospitals are required to submit one of three things: Data via QRDA I file, a zero denominator declaration, or a case threshold exemption. Of these three options, submission of data via QRDA I file is the most burden-intensive. For both hybrid measures, our currently approved burden estimates assume data submission via QRDA I file for all IPPS hospitals; therefore, we do not believe this modification results in an increase in burden.

k. Information Collection Burden Estimate for the Modification of the eCQM Validation Policy Medical Record Requests Beginning With the FY 2025 Payment Determination

In section IX.E.11.b. of the preamble of this final rule, we are modifying our eCQM validation policy to increase the reporting of medical requests from at least 75 percent of records to 100 percent of records beginning with the FY 2025 payment determination and for subsequent years.

In the FY 2017 IPPS/LTCH PPS final rule, we finalized to require submission of at least 75 percent of sampled eCQM medical records in a timely and complete manner (81 FR 57181). While we adopted a policy to require submission of at least 75 percent of sampled records, we estimated the burden associated with this finalized policy with the assumption that hospitals would submit 100 percent of sampled eCQM medical records (81 FR 57261). Based on this estimate, we believe the currently approved burden already encompasses burden associated with our finalized policy.

l. Information Collection Burden Estimate To Add Reporting and Submission Requirements for PRO–PMs Beginning With the FY 2026 Payment Determination

In section IX.E.10.k. of the preamble of this final rule, we are adopting reporting and submission requirements for PRO–PMs beginning with the FY 2026 payment determination. Our policy does not yield a change in burden beyond that which is discussed in section X.B.6.e. of the preamble of this final rule for the THA/TKA PRO–PM.

m. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022 (expiration date December 31, 2022), we estimate that the policies promulgated in this final rule will result in a total increase of 746,300 hours annually for 3,150 IPPS hospitals from the CY 2023 reporting period/FY 2025 payment determination through the CY 2026 reporting period/FY 2028 payment determination. The total cost increase related to this information collection is approximately $23,437,906. The subsequent tables summarize the total burden changes for each respective FY payment determination compared to our currently approved information collection burden estimates (the table for the FY 2028 payment determination reflects the total burden change associated with all proposals). For the THA/TKA PRO–PM, only one survey will be administered during the CY 2023 reporting period due to the start of reporting occurring in 3Q and the beginning of mandatory reporting would take place in 3Q of the CY 2025 reporting period. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1022 which expires December 31, 2022.

SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2023 REPORTING PERIOD/FY 2025 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2023 Reporting Period / FY 2025 Payment Determinations							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per hospital**	**Newly Finalized Annual burden (hours) across hospitals**	**Previously finalized annual burden (hours) across hospitals**	**Net difference in annual burden hours**
Add Hospital Commitment to Health Equity Structural Measure	10	1	3,150	1	.167	525	N/A	+525
Add Screening for Social Drivers of Health Measure (Survey)	2	N/A	5,250,000	N/A	111.1	175,000	N/A	+175,000
Add Screening for Social Drivers of Health Measure (Reporting)	10	1	1,575	1	0.167	273	N/A	+263
Add Screen Positive Rate for Social Drivers of Health	10	1	1,575	1	0.167	273	N/A	+263
Add THA/TKA PRO-PM Measure (Survey Completion)	7.25	N/A	1,575	N/A	1.58	2,492	N/A	+2,492
Add THA/TKA PRO-PM Measure (Data Submission)	10	1	1,575	1	0.167	263	N/A	+263
	Total Change in Information Collection Burden Hours: +178,568							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+178,568) = **+$5,602,913**							

SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD/FY 2026 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2024 Reporting Period / FY 2026 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per hospital**	**Newly Finalized burden (hours) across respondent**	**Previously finalized annual burden (hours) across respondent**	**Net difference in annual burden hours**
Add Hospital Commitment to Health Equity Structural Measure	10	1	3,150	1	.167	525	N/A	+525
Add Screening for Social Drivers of Health Measure (Survey)	2	N/A	21,000,000	N/A	222.2	700,000	N/A	+700,000
Add Screening for Social Drivers of Health Measure (Reporting)	10	1	3,150	1	0.167	525	N/A	+525
Add Screen Positive Rate for Social Drivers of Health	10	1	3,150	1	0.167	,525	N/A	+525
Add THA/TKA PRO-PM Measure (Survey)	7.25	N/A	1,575	N/A	4.75	7,477	N/A	+7,477
Add THA/TKA PRO-PM Measure (Reporting)	10	2	1,575	1	0.33	525	N/A	+525
Modify eCQM Reporting	60	4	3,150	1	1	12,600	8,800	+3,800
	Total Change in Information Collection Burden Hours: +713,377							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+713,377) = **+$22,401,251**							

SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/FY 2027 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2025 Reporting Period / FY 2027 Payment Determinations							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per hospital**	**Newly finalized annual burden (hours) across respondent**	**Previously finalized annual burden (hours) across respondent**	**Net difference in annual burden hours**
Add Hospital Commitment to Health Equity Structural Measure	10	1	3,150	1	.167	525	N/A	+525
Add Screening for Social Drivers of Health Measure (Survey)	2	N/A	21,000,000	N/A	222.2	700,000	N/A	+700,000
Add Screening for Social Drivers of Health Measure (Reporting)	10	1	3,150	1	0.167	525	N/A	+525
Add Screen Positive Rate for Social Drivers of Health	10	1	3,150	1	0.167	525	N/A	+525
Add THA/TKA PRO-PM Measure – Voluntary Reporting (Survey)	7.25	N/A	1,575	N/A	3.16	4,984	N/A	+4,984
Add THA/TKA PRO-PM Measure – Voluntary Reporting (Reporting)	10	1	1,575	1	0.167	262.5	N/A	+262.5
Add THA/TKA PRO-PM Measure – Mandatory Reporting (Survey)	7.25	N/A	3,150	N/A	6.33	19,938	N/A	+19,938
Add THA/TKA PRO-PM Measure – Mandatory Reporting (Reporting)	10	1	3,150	1	0.33	525	N/A	+525
Modify eCQM Reporting	60	4	3,150	1	1	12,600	8,800	+3,800
	Total Change in Information Collection Burden Hours: +731,084							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+731,084) = **+$22,958,594**							

SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/FY 2028 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2026 Reporting Period / FY 2028 Payment Determinations							
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per hospital	New finalized annual burden (hours) across respondent	Previously finalized annual burden (hours) across respondent	Net difference in annual burden hours
Add Hospital Commitment to Health Equity Structural Measure	10	1	3,150	1	.167	525	N/A	+525
Add Screening for Social Drivers of Health Measure (Survey)	2	N/A	21,000,000	N/A	222.2	700,000	N/A	+700,000
Add Screening for Social Drivers of Health Measure (Reporting)	10	1	3,150	1	0.167	525	N/A	+525
Add Screen Positive Rate for Social Drivers of Health	10	1	3,150	1	0.167	525	N/A	+525
Add THA/TKA PRO-PM Measure (Survey)	7.25	N/A	3,150	N/A	12.66	39,875	N/A	+39,875
Add THA/TKA PRO-PM Measure (Reporting)	10	2	3,150	1	0.33	1,050	N/A	+1,050
Modify eCQM Reporting	60	4	3,150	1	1	12,600	8,800	+3,800
	Total Change in Information Collection Burden Hours: +746,300							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+746,300) = **+$23,437,906**							

8. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

OMB has currently approved 0 hours of burden under OMB control number 0938–1175 (expiration date January 31, 2025), accounting for the information collection requirements for 11 PCHs for the FY 2024 program year.

For more detailed information on our finalized policies for the PCHQR Program, we refer readers to section IX.F. of the preamble of this final rule. We are: (1) adopting and codifying a patient safety exemption for the measure removal policy; (2) beginning public display of the End-of-Life (EOL) measures with modification to begin with FY 2025 program year data; and (3) beginning public display of the 30-Day Unplanned Readmissions for Cancer Patients measure beginning with FY 2024 program year data. These new requirements do not impact our currently approved information collection burden estimates.

We did not receive comments regarding the ICRs for the PCHQR Program.

9. ICRs for the Medicare Promoting Interoperability Program

a. Historical Background

In section IX.H. of the preamble of this final rule, we discussed several policies for the Medicare Promoting Interoperability Program. An information collection request under OMB control number 0938–1278 (expiration date July 31, 2022) reflecting program policies finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45514) is pending approval, which

includes an estimated total burden of 21,450 hours and $879,450, accounting for information collection burden experienced by approximately 3,300 eligible hospitals that attest to CMS under the Medicare Promoting Interoperability Program. We will be submitting an updated information collection request under OMB control number 0938–1278 in connection with this FY 2023 IPPS/LTCH PPS final rule that will reflect the inclusion of CAHs and additional new information pertinent to the collection requirements. The collection of information burden analysis in this final rule focuses on all eligible hospitals and CAHs that could participate in the Medicare Promoting Interoperability Program and attest to the objectives and measures, and report eCQMs, under the Medicare Promoting Interoperability Program for the EHR reporting periods in CY 2023, CY 2024, and CY 2025.

For more detailed information on our finalized policies for the Medicare Promoting Interoperability Program, we refer readers to section IX.H. of the preamble of this final rule. We are finalizing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program that we expect to affect our collection of information burden estimates: (1) requiring the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure beginning in the CY 2023 electronic health record (EHR) reporting period while maintaining its associated points at 10 points and with the two exclusions that we proposed and an additional exclusion based on public comment; (2) adopting a new Antimicrobial Use and Resistance (AUR) Surveillance measure that will be required for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program's Public Health and Clinical Data Exchange Objective with associated exclusions beginning with the CY 2024 EHR reporting period, and (3) requiring eligible hospitals and CAHs to submit their level of active engagement in addition to submitting responses for the Public Health and Clinical Data Exchange Objective required measures and the optional measures beginning with the CY 2023 EHR reporting period. We are also modifying our eCQM reporting and submission requirements whereby we are increasing the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period. Details on these policies and associated burden changes are discussed further in this section of this final rule.

We are also finalizing several policies which will not affect the information collection burden associated with the Medicare Promoting Interoperability Program. As discussed in section IX.H.10.a.(2) of the preamble to this final rule, we are adopting four eCQMs: (1) Severe Obstetric Complications eCQM with inclusion in the eCQM measure set beginning with the CY 2023 reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period; (2) Cesarean Birth (ePC–02) eCQM with inclusion in the eCQM measure set beginning with the CY 2023 reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period; (3) Hospital-Harm—Opioid-Related Adverse Events eCQM with inclusion in the eCQM measure set beginning with the CY 2024 reporting period; and (4) Global Malnutrition Composite Score eCQM with inclusion in the eCQM measure set beginning with the CY 2024 reporting period. We are also: (1) expanding the Query of PDMP measure to include not only Schedule II opioids, but also Schedule III and IV drugs, beginning with the EHR reporting period in CY 2023; (2) adding the Enabling Exchange Under TEFCA measure to the Health Information Exchange Objective as an optional alternative to the three existing measures and updating the scoring methodology for the Health Information Exchange Objective beginning with EHR reporting period in CY 2023; (3) reducing the active engagement options for the Public Health and Clinical Data Exchange Objective from three to two options beginning with the CY 2023 EHR reporting period; (4) modifying the scoring methodology for the Medicare Promoting Interoperability Program beginning with EHR reporting period in CY 2023; (5) instituting public reporting of certain Medicare Promoting Interoperability Program data beginning with data from EHR reporting period in CY 2023; and (6) removing regulation text for the objectives and measures under 42 CFR 495.24(e) and adding new paragraph (f) beginning in CY 2023.

The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $21.20 per hour for a medical records and health information technician professional.[1167] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in publicly available literature. Nonetheless, we believe that doubling the hourly wage rate ($21.20 × 2 = $42.40) to estimate total cost is a reasonably accurate estimation method and is consistent with OMB guidance. Accordingly, we will calculate cost burden to hospitals using a wage plus benefits estimate of $42.40 per hour throughout the discussion in this section of this rule for the Medicare Promoting Interoperability Program.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45514), our burden estimates were based on an assumption of 3,300 eligible hospitals and CAHs. We have determined that our assumption was in error as we inadvertently omitted the number of CAHs in our estimate. For this final rule, we are updating our assumption to 3,150 eligible hospitals and 1,350 CAHs based on data from the CY 2020 EHR reporting period, for a total number of 4,500 respondents. These estimates differ from those of the information collection request under OMB control number 0938–1278 as they are based on updated data from the CY 2020 EHR reporting period and reflect the addition of the number of CAHs. As indicated earlier, an updated information collection request will be submitted with updated numbers inclusive of CAHs. We are making this adjustment to reflect the total number of potential eligible hospitals and CAHs that could report under the Medicare Promoting Interoperability Program.

b. Information Collection Burden Estimate for the Electronic Prescribing Objective's Query of PDMP Measure Beginning with the CY 2023 EHR Reporting Period

In section IX.H.3.c.(2) of the preamble of this final rule, we are requiring the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program beginning in CY 2023 and maintain the associated points at 10 points.

In the FY 2020 IPPS/LTCH PPS final rule, we estimated the burden associated with reporting the Electronic Prescribing Objective and associated measures to be 10 minutes (84 FR 42608) coinciding with the finalized change to the Query of PDMP measure to require a ''yes/no'' response instead of a numerator/denominator calculation.

[1167] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records and Health Information Technicians. Accessed on January 13, 2022. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

However, the burden associated with the Query of PDMP measure was not accounted for in the burden estimate of 10 minutes for the Electronic Prescribing Objective in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42608 through 42609), the FY 2021 IPPS/LTCH PPS final rule (85 FR 59014), or the FY 2022 IPPS/LTCH PPS final rule (86 FR 45516). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45464), we finalized that the Query of PDMP measure will remain optional. As a result of the finalized policy to require the Query of PDMP measure beginning with the EHR reporting period in CY 2023, and considering the burden estimate of 30 seconds (0.5 minutes) for similar ''yes/no'' response measures for the Public Health and Clinical Data Exchange Objective as reflected in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45515), we have updated our burden estimate for the Electronic Prescribing Objective to 10.5 minutes to reflect the additional burden of reporting the Query of PDMP measure. Therefore, we estimate a total increase in burden of 38 hours across all eligible hospitals and CAHs (0.5 minutes × 4,500 eligible hospitals and CAHs) annually at a cost of $1,590 (38 hours × $42.40).

In addition, in section IX.H.3.c.(3) of the preamble of this final rule, we are refining the Query of PDMP measure to include not only Schedule II opioids, but also Schedule III and IV drugs, beginning with EHR reporting period in CY 2023. Our policy will not yield a change in burden as it does not affect the requirements for data submission for eligible hospitals or CAHs as we continue to assume all eligible hospitals and CAHs will report this measure once per year.

c. Information Collection Burden Estimate for the Antimicrobial Use and Resistance (AUR) Surveillance Measure Beginning With the CY 2024 EHR Reporting Period

In section IX.H.5.b. of the preamble of this final rule, we are finalizing the requirement to report a new Antimicrobial Use and Resistance (AUR) Surveillance measure for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program's Public Health and Clinical Data Exchange Objective with a modification to delay the beginning of reporting until the EHR reporting period in CY 2024 instead of the EHR reporting period in CY 2023. Eligible hospitals and CAHs will be required to attest to active engagement with CDC's National Healthcare Safety Network (NHSN) to submit AUR data and receive a report from NHSN indicating their successful submission of AUR data for the EHR reporting period.

In the FY 2022 IPPS/LTCH PPS final rule, we finalized that eligible hospitals and CAHs are required to report four measures for the Public Health and Clinical Data Exchange Objective with a total estimated burden of 2 minutes annually (30 seconds × 4 measures) (86 FR 45516). Therefore, we estimate the burden associated with this new measure to be 30 seconds, or 0.5 minutes, per eligible hospital or CAH annually. We estimate a total increase in burden of 38 hours across all eligible hospitals and CAHs (0.5 minutes × 4,500 eligible hospitals and CAHs) annually at a cost of $1,611 (38 hours × $42.40).

While the burden associated with attesting to active engagement for the AUR Surveillance measure will be accounted for under OMB control number 0938–1278 (expiration date July 31, 2022), the burden associated with the actual submission of AUR data to NHSN is accounted for under OMB control number 0920–0666 (expiration date January 31, 2025).

d. Information Collection Burden Estimate for the Policy To Require Eligible Hospitals and CAHs To Submit Their Level of Active Engagement for the Public Health and Clinical Data Exchange Objective

In section IX.H.5.c.(3) of the preamble of this final rule, we are requiring eligible hospitals and CAHs to submit their level of engagement for the measures under the Public Health and Clinical Data Exchange Objective, either Pre-production and Validation or Validated Data Production. This requirement is in addition to submitting responses for the required measures and the optional measures, if applicable.

The burden associated with this requirement is similar to the burden associated with the attestation that eligible hospitals and CAHs must complete for the four previously finalized measures under this objective and the finalized AUR Surveillance measure. Therefore, we estimate the burden associated with this new requirement to be 30 seconds, or 0.5 minutes, per eligible hospital or CAH annually. We estimate a total increase in burden of 38 hours across all eligible hospitals and CAHs (0.5 minutes/hospital × 4,500 eligible hospitals and CAHs) annually at a cost of $1,611 (38 hours × $42.40).

In addition, in section IX.H.c.(2) of the preamble of this final rule, we are reducing the active engagement options for the Public Health and Clinical Data Exchange Objective from three to two options beginning with EHR reporting period in CY 2023. We are delaying the requirement that eligible hospitals and CAHs may spend only one EHR reporting period at the pre-production and validation phase until the EHR reporting period in CY 2024. Our policy will not yield a change in burden as it does not affect the requirements for data submission for eligible hospitals or CAHs but instead will motivate health IT vendors to implement these capabilities in their products and encourage healthcare organizations to engage in these reporting activities.

e. Information Collection Burden Estimate for the Modification of the eCQM Reporting and Submission Requirements Beginning With the CY 2024 Reporting Period

In section IX.H.10.b of the preamble of this final rule, we are modifying our eCQM reporting and submission requirements whereby we are increasing the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period. In addition, the six eCQMs must be comprised of: (1) Three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the finalized Severe Obstetric Complications eCQM; and (4) the finalized Cesarean Birth eCQM, for a total of six eCQMs.

We previously finalized in the FY 2021 IPPS/LTCH PPS final rule that, for the CY 2023 reporting period, eligible hospitals and CAHs are required to submit data for three self-selected eCQMs each year and the Safe Use of Opioids-Concurrent Prescribing eCQM for a total of four eCQMs (85 FR 58975). We also finalized in the FY 2021 IPPS/LTCH PPS final rule to require eligible hospitals and CAHs to submit four quarters of eCQM data beginning in the CY 2023 reporting period (85 FR 58975). We continue to estimate the information collection burden associated with the eCQM reporting and submission requirements to be 10 minutes per measure per quarter. As discussed in the section IX.E.4.f. of the preamble of this final rule, we already account for the burden associated with the reporting of eCQM measures for eligible hospitals as part of the Hospital Inpatient Quality Reporting Program, therefore the burden for the 3,150 eligible hospitals is included there. For the submission of six eCQM measures for CAHs, we estimate a total of 1 hour (0.167 hours/eCQM × 6 eCQMs) per CAH per quarter. We estimate a total burden of 1,350 hours across all CAHs (1 hour × 1,350 CAHs) for each quarter of eCQM data or 5,400 hours annually (1,350 hours × 4

quarters) at a cost of $228,960 (5,400 hours × $42.40/).

f. Information Collection Burden Estimate for the Adoption of Two eCQMs Beginning With the CY 2023 Reporting Period and Two eCQMs Beginning With the CY 2024 Reporting Period

In section IX.H.10.a. of the preamble of this final rule, we are adopting four eCQMs: (1) Severe Obstetric Complications eCQM beginning with the CY 2023 reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period; (2) Cesarean Birth (ePC–02) eCQM beginning with the CY 2023 reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period; (3) Hospital-Harm—Opioid-Related Adverse Events eCQM beginning with the CY 2024 reporting period; and (4) Global Malnutrition Composite Score eCQM beginning with the CY 2024 reporting period.

The addition of these four eCQMs do not affect the information collection burden of submitting eCQMs under the Medicare Promoting Interoperability Program beyond the burden described in section IX.B.4.f. of the preamble of this final rule. Current Medicare Promoting Interoperability Program policy requires hospitals to submit data for three self-selected eCQMs each year and the Safe Use of Opioids-Concurrent Prescribing eCQM for a total of four eCQMs (85 FR 58975). In other words, although these new eCQMs are being added to the eCQM measure set, hospitals are not required to report more than a total of six eCQMs as discussed in section IX.10. of the preamble of this final rule.

With respect to any costs unrelated to data submission, we refer readers to section I.K. of Appendix A of this final rule.

g. Information Collection Burden Estimate To Add the Enabling Exchange Under TEFCA Measure to the Health Information Exchange Objective Beginning With the CY 2023 EHR Reporting Period

In section IX.H.4.c. of the preamble of this final rule, we are adding the Enabling Exchange Under TEFCA measure to the Health Information Exchange Objective as an optional alternative to the three existing measures (Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, or the HIE Bi-Directional Exchange measure) and updating the scoring methodology for the Health Information Exchange Objective beginning with EHR reporting period in the CY 2023. Our policy does not yield a change in burden as eligible hospitals and CAHs may choose to report the two Support Electronic Referral Loop measures, or may choose to report the HIE Bi-Directional Exchange measure, or may choose to report the new Enabling Exchange Under TEFCA measure.

h. Information Collection Burden Estimate To Modify the Scoring Methodology for the Medicare Promoting Interoperability Program Beginning With the CY 2023 EHR Reporting Period

In section IX.H.6. of the preamble of this final rule, we are finalizing the following changes to the scoring methodology:

- Increasing the points allocated to the Public Health and Clinical Data Exchange Objective from 10 points to 25 points,
- Increasing the points allocated to the Electronic Prescribing Objective from 10 points to 20 points,
- Decreasing the points allocated to the Health Information Exchange Objective from 40 points to 30 points, and
- Decreasing the points allocated to the Provide to Patient Exchange Objective from 40 points to 25 points.

Our policy does not yield a change in burden as it does not affect the requirements for data submission for eligible hospitals or CAHs but only changes the scoring methodology.

i. Information Collection Burden Estimate To Institute Public Reporting of Medicare Promoting Interoperability Program Data Beginning With Data From the CY 2023 EHR Reporting Period

In section IX.H.7. of the preamble of this final rule, we are finalizing to publicly report certain Medicare Promoting Interoperability Program data submitted by eligible hospitals and CAHs beginning with EHR reporting period in CY 2023. Specifically, we are finalizing that we will publish eligible hospitals' and CAHs' actual scores and their CMS EHR certification ID, beginning with data submitted for the CY 2023 EHR reporting period. Our policy does not yield a change in burden as it does not affect the requirements for data submission for eligible hospitals or CAHs.

j. Information Collection Burden Estimate for Modifications to Regulatory Text

In section IX.H.8. of the preamble of this final rule, we are removing references to objectives and measures and making modifications to regulatory text at 42 CFR 495.24 beginning in CY 2023. Our policy does not yield a change in burden as it does not affect the requirements for data submission for eligible hospitals or CAHs since the changes only modify regulatory text.

k. Summary of Estimates Used To Calculate the Collection of Information Burden

In summary, under OMB control number 0938–1278 (expiration date July 31, 2022), we estimate that the policies in this final rule result in a total increase in burden of 5,513 hours through the CY 2024 EHR reporting period. The total cost increase related to this information collection is approximately $233,730 (5,513 hours × $42.40) across 4,500 eligible hospitals and CAHs. The tables summarize the total burden changes for the CY 2023 and for CY 2024 EHR reporting periods compared to our currently approved information collection burden estimates (the table for the CY 2024 EHR reporting period reflects the total burden change associated with all policies being finalized).

In the FY 2022 IPPS/LTCH PPS final rule, we estimated each eligible hospital and CAH would require 6.5 hours annually to participate in the Medicare Promoting Interoperability Program (86 FR 45517). As a result of the policies in this final rule, we estimate the new total annual burden to be 6.6 hours per eligible hospital and CAH as well as an additional 4 hours annually for CAHs to report eCQMs. Therefore, we estimate the adjustment in the number of eligible hospitals and CAHs from 3,300 to 4,500 results in an increase of approximately +13,290 hours ((6.6 hours × −150 eligible hospitals) + (10.6 hours × 1,350 CAHs)) at a cost of +$563,496 (+13,290 hours × $42.40).

We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1278 (expiration date July 31, 2022).

SUMMARY OF ANNUAL MEDICARE PROMOTING INTEROPERABILITY PROGRAM INFORMATION COLLECTION BURDEN CHANGES FOR THE CY 2023 EHR REPORTING PERIOD

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1278							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of eligible hospitals/CAHs reporting**	**Average number records per eligible hospital or CAH per quarter**	**Annual burden (hours) per eligible hospital/ CAH**	**Newly Finalized annual burden (hours) across eligible hospitals/CAHs**	**Previously finalized annual burden (hours) across eligible hospitals/CAHs**	**Net difference in annual burden hours**
Require Query of PDMP measure	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
Require Active Engagement Reporting	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
	Total Change in Information Collection Burden Hours: +75							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (+75) = **+$3,180**							

SUMMARY OF ANNUAL MEDICARE PROMOTING INTEROPERABILITY PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 EHR REPORTING PERIOD

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1278							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of eligible hospitals/CAHs reporting**	**Average number records per hospital or CAH per quarter**	**Annual burden (hours) per eligible hospital/ CAH**	**Newly Finalized annual burden (hours) across eligible hospitals/CAHs**	**Previously finalized annual burden (hours) across eligible hospitals/CAHs**	**Net difference in annual burden hours**
Require Query of PDMP measure	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
Add Antimicrobial Use and Resistance (AUR) Surveillance measure	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
Require Active Engagement Reporting	0.5	1	4,500	1	0.0083	37.5	N/A	+37.5
Modify eCQM Reporting	20	4	1,350	1	1.33	5,400	N/A	+5,400
	Total Change in Information Collection Burden Hours: +5,513							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (+5,513) = **+$233,730**							

We did not receive comments regarding the ICRs for the Medicare Promoting Interoperability Program.

10. ICRs for the Codification of the Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans

As discussed in section X.A. of the preamble of this final rule, we are finalizing proposed codifications and clarifications for certain policies relating to Deferred Compensation. This finalized provision will not change our current policies for allowable Deferred Compensation costs associated with Qualified and Non-Qualified Deferred Compensation Plans that are included in Medicare cost reports. The documentation requirements will require that a provider of services must maintain and make available to its contractor and CMS, documentation to substantiate the costs incurred for the plans included in its Medicare cost report. These documentation requirements are based on the recordkeeping requirements at current § 413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under Medicare. The OMB control number for this information collection request is 0938–0050, which expired on March 31, 2022. A 30-day **Federal Register** notice published on June 22, 2022 (87 FR 37338) for the reinstatement of the information collection request. The comment period closed July 22, 2022.

We did not receive comments regarding the ICRs for the codification of the costs incurred for qualified and non-qualified deferred compensation plans.

11. ICRs for Condition of Participation (CoP) Requirements for Hospitals and CAHs To Continue Reporting Data for COVID–19 and Influenza After the PHE Ends as Determined by the Secretary

a. Continued COVID–19 and Seasonal Influenza Reporting

We are finalizing proposed revisions the regulations by adding provisions to the CoPs (§ 482.42 for hospitals and § 485.640 for CAHs) requiring hospitals and CAHs, after the conclusion of the current COVID–19 PHE, to continue COVID–19 and seasonal influenza-related reporting. The revisions will continue to apply upon conclusion of the COVID–19 Public Health Emergency (PHE) and would continue until April 30, 2024, unless the Secretary establishes an earlier ending date. The data elements align closely with those COVID–19 reporting requirements for long-term care (LTC) facilities that were finalized on November 9, 2021 (86 FR 62421) and are representative of the guidance provided to hospitals and CAHs for reporting. Therefore, we do not expect that these categories of data elements will require hospitals and CAHs to report any information beyond that which they have already been reporting. Furthermore, similar to the requirements for LTC facilities, this provision will also allow for the scope and frequency of data collection to be reduced and limited responsive to the evolving clinical and epidemiological circumstances.

Specifically, as discussed in section XX.B.2 of the preamble of this final rule, we have re-evaluated the proposed data elements in consideration of the feedback shared by commenters and the evolving state of the current PHE and are modifying our proposal to remove the following from the list of required data categories to report:

- Suspected COVID–19 infections among patients and staff
- Confirmed COVID–19 and influenza infections among staff
- COVID–19 and influenza deaths among staff
- Confirmed co-morbid influenza and COVID–19 infections among staff

Although data pertaining to suspected cases were valuable throughout the COVID–19 PHE, particularly in instances when testing supplies were limited and cases were often identified based on clinical signs and symptoms, this information is less meaningful now that testing supplies are readily available to confirm the presence of infection. Thus, we do not believe suspected COVID–19 infection data would be necessary to collect from hospitals and CAHs once the PHE declaration ends, and therefore, we removed this data category.

The data categories for staff (suspected infections among staff; confirmed COVID–19, influenza, and co-morbid infections among staff; COVID–19 and influenza deaths among staff) have not been among the information that hospitals and CAHs were required to report throughout the COVID–19 PHE. Hospitals and CAHs were required to report suspected, confirmed, and comorbid infections, as well as deaths, for patients only. In the proposed rule, CMS did not intend to extend these data categories to include staff. The inclusion of staff in the proposed rule for these data categories was a technical error; therefore, we removed these data categories.While beneficial during an active PHE and the specific circumstances of the COVID–19 PHE, we believe the above data categories are not necessary to provide the most valuable information during a post-PHE state for continued monitoring and as such we are removing these data categories to be responsive to commenter concerns regarding increased burden on facilities and staff, while also attempting to provide quality care for patients.

The data categories that we are finalizing in this rule that hospitals and CAHs will be required to report relevant to COVID–19, to the extent as determined by the Secretary, are as follows: Confirmed infections among patients; Total deaths among patients; Personal protective equipment and testing supplies; Ventilator use, capacity, and supplies; Total bed and intensive care unit bed census and capacity; Vaccine administration data of patients and staff; and Relevant therapeutic inventories or usage, or both. The data categories that we are finalized in this rule that hospitals and CAHs will be required to report relevant to influenza, to the extend as determined by the Secretary, are as follows: Confirmed infections among patients; Total deaths among patients; and Confirmed co-morbid influenza and COVID–19 infections among patients. We believe these data will offer the most valuable information during a post-PHE state by continuing to capture critical information on COVID–19 and seasonal influenza for ongoing surveillance and to inform any potential action to protect patient health and safety. As previously discussed, these data will enable the federal government to monitor the ability of facilities to provide safe care for patients by determining the number of COVID–19 and influenza infections being treated by facilities; the quantity of resources available to facilities and the volume of resources they are using; and facilities' continued capacity to provide safe patient care. In addition, as done throughout the COVID–19 pandemic, local, state, and federal authorities will continue to use these data to identify possible resurgence in cases and outbreaks, for resource allocation purposes, and to update guidance pertaining to the safe provision of patient care.

As indicated in the proposal, we do not expect continued daily reporting for COVID–19 or influenza outside of a declared PHE. Moreover, the rule allows for the scope of data categories and frequency of data collection and reporting to be reduced and limited, as determined by the Secretary, responsive to evolving clinical and epidemiology circumstances. This approach to reducing the proposed set of required data categories will provide a path towards winding down the overall

reporting of COVID–19-related data between the end of the current PHE and April 2024 when these requirements will sunset. These requirements will not be implemented and enforced until the current COVID–19 PHE declaration concludes, and CMS will issue guidance indicating such a transition. As discussed previously, we expect the method of notification to follow a model similar to that which we used to inform regulated entities at the beginning of the COVID–19 PHE (see QSO–21–03–Hospitals/CAHs at *https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0*). The data that hospitals and CAHs will be required to report are consistent with the information they have already been reporting throughout the COVID–19 PHE (OMB control numbers 0938–0328 for hospitals and 0938–1043 for CAHs).

For purposes of burden estimates, we do not differentiate among hospitals and CAHs as they all will complete the same data collection.

For the estimated costs contained in the analysis that follows, we used data from the U.S. Bureau of Labor Statistics (BLS) to determine the mean hourly wage for the staff member responsible for reporting the required information for a hospital (or a CAH).[1168] Based on our experience with hospitals and CAHs and the current COVID–19 and related reporting requirements, we believe that this will primarily be the responsibility of a registered nurse and we have used this position in this analysis at an average hourly salary of $39.27. For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. Therefore, we estimated the total hourly cost for a registered nurse to perform these duties would be $79.

According to the most recent COVID–19 hospital reporting guidance (available at *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf*), hospitals are reporting COVID–19 and influenza-related data on a daily basis, with backdating permitted for weekends and holidays, except psychiatric and rehabilitation hospitals who report weekly. Some data element reporting fields are inactive for data collection, and therefore, hospitals can optionally report data for these fields. The inactive fields and active fields together reflect what is listed in this final rule for continued COVID–19 and influenza-related reporting as well as future reporting in the event of a declared PHE, which we discuss next. We do not expect, nor did we propose, continued daily reporting for COVID–19 or influenza outside of a declared PHE. If we were to assume a weekly reporting frequency, we would anticipate that there are reduced cases and fewer data elements (with no line level patient data) being reported. Based on these assumptions, we estimated that total annual burden hours for all participating hospitals and CAHs to comply with these requirements would be 483,600 hours based on weekly reporting of the required information by approximately 6,200 hospitals and CAHs × 52 weeks per year and at an average weekly response time of 1.5 hours for a registered nurse with an average hourly salary of $79. Therefore, the estimate for total annual costs for all hospitals and CAHs to comply with the required reporting provisions weekly would be $38,204,400 or approximately $6,162 per facility annually. We acknowledge that the data elements and reporting frequency could increase or decrease over the next 2 years, and those changes would impact this burden estimate.

We note that this estimate is assumed to be a 1-day snapshot of reporting information as opposed to a cumulative weekly report accounting for information based on each day of that week. If we assumed a cumulative weekly account, we can assume reduced burden related to the actual reporting time, but anticipate that the estimate would be slightly higher to account for the need to track closely to daily reporting. We also acknowledged that respondents may have to track and invest in infrastructure in order to timely and accurately report on the specified frequency. Thus, respondents may face ongoing burdens associated with this collection even in the case of reduced frequency of submissions. We solicited comment on this potentiality.

Furthermore, we note that this estimate likely overestimates the costs associated with reporting because it assumes that all hospitals and CAHs will report manually. Efforts are underway to automate hospital and CAH reporting that have the potential to significantly decrease reporting burden and improve reliability. Our preliminary estimates for these reporting activities (OMB control numbers 0938–0328 for hospitals and 0938–1043 for CAHs) can be found in the tables that follow.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent (low range – high range)	Average Burden per Response (in hours)	Total Burden Hours (low range – high range)
Hospitals and CAHs	Standardized format as determined by the Secretary	6,200	52	1.5	483,600
Total					483,600

[1168] BLS. *May 2020 National Occupational Employment and Wage Estimates United* States. United States Department of Labor. Accessed at *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed on August 25, 2021.

ESTIMATED ANNUALIZED RESPONDENT BURDEN COSTS			
Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Hospital and CAH Staff—Registered Nurses	483,600	* $79	$38,204,400
Total			$38,204,400

b. Future Reporting in the Event of a PHE Declaration

In addition, we proposed to establish reporting requirements for future PHEs related to infectious diseases by requiring hospitals and CAHs to electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS–CoV–2/COVID–19, and other viral and bacterial pathogens or infectious diseases of pandemic or epidemic potential only when the Secretary has declared a PHE directly related to such specific pathogens and infectious diseases. Specifically, we proposed that when the Secretary has declared a PHE, hospitals and CAHs would be required to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary.

We also proposed to require that a hospital (or a CAH) would be required to report each applicable infection (confirmed and suspected) and the applicable vaccination data in a format that provides person-level information, to include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients, unless the Secretary specifies an alternative format by which the hospital (or CAH) would be required to report these data elements. Lastly, we proposed that a hospital (or a CAH) would provide the information specified on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) or other CDC-supported surveillance systems as determined by the Secretary. We noted that in this final rule, we have withdrawn this proposal to establish requirements for hospitals and CAHs to report certain data in the event of a future PHE declaration.

We solicited comment on the burden associated with these proposed requirements given the intended flexibility provided in reducing or limiting the scope and frequency of reporting based on the state of the PHE and ongoing circumstances, requested comment on the potential burden associated with the proposed reporting requirements as they might relate to any differences in the public health response to one specific pathogen or infectious disease versus another that would be directly related to the declared PHE, and requested public comments addressing burden estimates (and the potential differences in those estimates) for variations in the required reporting response for a local PHE versus a regional PHE versus a national PHE that might be declared by the Secretary based on the specific circumstances at the time of the declaration.

Comment: A few commenters indicated that our cost estimate for continued COVID–19-related data reporting was inaccurate and underestimated. The commenters stated that collecting and reporting these data involves multiple staff from nursing, human resources, medical staff, infection prevention and control, laboratory, respiratory, materials, pharmacy, and information technology departments, and these staff have had to repeatedly adjust how they collect and report data in response to changes in guidance throughout the COVID–19 PHE while also performing their other duties. Likewise, a few commenters indicated that data collection and reporting was solely performed by infection prevention and control staff, while and other commenters stated that quality staff solely compiled and reported the data. One commenter also noted that lost revenue due to nursing staffing having to devote time and resources to non-direct care activities, such as manual data collection/reporting, and the current staffing shortages, should also be considered in the burden estimate acknowledging that this is an opportunity cost that is difficult to quantify.

Response: We agree that data collection and reporting procedures, including but not limited to the number and type of staff involved (job title, direct care or non-direct care) vary among hospitals and CAHs. After reviewing these comments and other feedback we received, we also believe the method of collecting the data (automated or manual) varies among hospitals and CAHs. As discussed in detail in section X.B. of this final rule, we modified our proposal to decrease the amount of data categories required for continued COVID–19-related reporting beginning at the conclusion of the current PHE. Specifically, we are finalizing the proposed revisions at § 482.42(e) and (f) and § 485.640(d) and (e) for hospitals and CAHs, respectively, with the following information no longer required to be reported: (1) Suspected COVID–19 infections among patients and staff, (2) Confirmed COVID–19 and influenza infections among staff, (3) COVID–19 and influenza deaths among staff, and (4) Confirmed co-morbid influenza and COVID–19 infections among staff. Given that this final rule decreases the scope of data categories and that the data collecting and reporting procedures among hospitals and CAHs varies, we believe the estimate reflects an accurate average burden.

Comment: With regard to reporting frequency and the burden associated, commenters provided various suggestions for the appropriate frequency of reporting including weekly, Mondays through Fridays only, while excluding holidays, and Mondays, Wednesdays, and Fridays only. One commenter noted that even if reporting were reduced from a daily requirement to once per week the burden would still be far greater than 1.5 hours per week. However, other commenters emphasized that, while more burdensome, standardized data reporting on a daily basis is necessary to detect trends and outbreaks in a timely manner and improves accuracy of real-time models developed to forecast spread of infectious diseases. Some commenters also noted the proposal as an unfunded mandate and indicated that CMS payment rates do not keep up with inflation rates.

Response: As noted in the proposed rule, we do not expect, nor did we propose, continued daily reporting for COVID–19 or seasonal influenza data outside of a declared PHE (87 FR 28642). We appreciate the suggestions from commenters and will consider them as decisions are made over the

next two years until this requirement sunsets in April 2024. Ultimately, the scope and frequency of reporting will be informed by the ongoing circumstances and evolving state of the public health response efforts.

13. Summary of All Burden in This Final Rule

The following chart reflects the total burden and associated costs for the ICRs presented in this section of this final rule.

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Hospital Wage Index	0	$0
Payment for Low-Volume Hospitals	0	$0
Hospital Inpatient Quality Reporting Program	+746,300	+$23,437,906
PPS-Exempt Cancer Hospital Quality Reporting Program	0	$0
Hospital Value-Based Purchasing Program	0	$0
Hospital-Acquired Condition Reduction Program	0	$0
Hospital Readmissions Reduction Program	0	$0
Medicare Promoting Interoperability Program	+13,290	+$563,496
Long Term Care Hospital Quality Reporting Program	0	$0
Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans	0	$0
CoP Requirements for Hospitals and CAHs to Continue Reporting Data for COVID-19 and Influenza After the PHE ends as Determined by the Secretary	+483,600	$38,204,400
TOTAL	**=1,243,190**	**=$62,205,402**

Chiquita Brooks-LaSure,
Administrator of the Centers for Medicare & Medicaid Services,
approved this document on July 22, 2022.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.24 is amended by adding paragraph (d)(3)(iii) to read as follows:

§ 412.24 Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

* * * * *

(d) * * *

(3) * * *

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for PCHs to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the PCHQR measure set. CMS will, upon removal of the measure—

(A) Provide notice to PCHs and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if PCHs continued to submit data on the measure; and

(B) Provide notice of the removal in the **Federal Register**.

* * * * *

■ 3. Section 412.60 is amended by revising paragraph (b) to read as follows:

§ 412.60 DRG classification and weighting factors.

* * * * *

(b) *DRG weighting factors.* CMS assigns, for each DRG, an appropriate weighting factor that reflects the estimated relative cost of hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups, subject to a maximum ten percent reduction to the weighting factor for a DRG as compared to the weighting factor for the same DRG for the prior fiscal year.

* * * * *

■ 4. Section 412.64 is amended by adding paragraph (h)(7) to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(h) * * *

(7) Beginning with fiscal year 2023, if CMS determines that a hospital's wage index value for a fiscal year would decrease by more than 5 percent as compared to the hospital's wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

* * * * *

■ 5. Section 412.103 is amended by adding paragraph (a)(8) to read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) * * *

(8) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area (as defined in § 412.64(b) and including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act).

* * * * *

■ 6. Section 412.106 is amended by—

■ a. Revising paragraph (g)(1)(ii);

■ b. In paragraph (g)(1)(iii)(C)(*8*), removing the phrase ''For each subsequent fiscal year,'' and adding in its place the phrase ''For fiscal year 2022,'';

■ c. Adding paragraphs (g)(1)(iii)(C)(*10*) and (*11*);

■ d. Redesignating paragraph (h) as paragraph (i); and

■ e. Adding a new paragraph (h).

The revisions and additions read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(ii) *Factor 2.* (A) For each of fiscal years 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured (and subtracting from the factor 0.1 percentage point for fiscal year 2014 and 0.2 percentage point for each of fiscal years 2015, 2016, and 2017), as determined by comparing—

(*1*) 18 percent, the percent of such individuals who are uninsured in 2013, based on the March 20, 2010, estimate of the ''Insured Share of the Nonelderly Population Including All Residents'' by the Congressional Budget Office.

(*2*) The percent of such individuals who are uninsured in the applicable fiscal year, based on the most recent estimate of the ''Insured Share of the Nonelderly Population Including All Residents'' by the Congressional Budget Office available at the time of development of the annual final rule for the hospital inpatient prospective payment system.

(B) For FY 2018 and subsequent fiscal years, a factor equal to 1 minus the percent change in the percent of individuals who are uninsured (and subtracting from the factor 0.2 percentage point for each of fiscal years 2018 and 2019), as determined by comparing the percent of individuals who are uninsured in—

(*1*) 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of the CMS); and

(*2*) The most recent period for which data is available (as so estimated and certified).

(iii) * * *

(C) * * *

(*10*) For fiscal year 2023, for all eligible hospitals, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from cost reports from the two most recent cost reporting years for

which audits have been conducted. If a hospital is a new hospital (that is, a hospital that began participation in the Medicare program after the two most recent cost reporting years for which audits have been conducted) or if the hospital is treated as a new hospital for purposes of Factor 3, the Medicare administrative contractor (MAC) will determine Factor 3 as the ratio of the hospital's uncompensated care costs from its FY 2023 cost report to the sum of uncompensated care costs for all DSH-eligible hospitals as estimated by CMS from the most recent cost reporting year for which audits have been conducted.

(*11*) For fiscal year 2024 and subsequent fiscal years, for all eligible hospitals, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from cost reports from the three most recent cost reporting years for which audits have been conducted. If a hospital is a new hospital (that is, a hospital that began participation in the Medicare program after the three most recent cost reporting years for which audits have been conducted) or if the hospital is treated as a new hospital for purposes of Factor 3, the Medicare administrative contractor (MAC) will determine Factor 3 as the ratio of the hospital's uncompensated care costs from its cost report for the applicable fiscal year to the sum of uncompensated care costs for all disproportionate share hospital (DSH)-eligible hospitals as estimated by CMS from the most recent cost reporting year for which audits have been conducted.

(h) *Supplemental payment for Indian Health Service and Tribal hospitals and Puerto Rico hospitals.* (1) For fiscal year 2023 and each subsequent fiscal year, Indian Health Service and Tribal Hospitals and Puerto Rico hospitals that qualify for an additional payment for uncompensated care under paragraph (g) of this section for the applicable fiscal year may also qualify to receive a supplemental payment.

(2) Indian Health Service and Tribal Hospitals and Puerto Rico hospitals that do not have a Factor 3 amount for fiscal year 2022 determined under paragraph (g)(1)(iii)(C)(*9*) of this section are not eligible to receive a supplemental payment under this paragraph (h).

(3) The amount of the supplemental payment for a fiscal year is determined as the difference between the following:

(i) A base year amount defined as the FY 2022 uncompensated care payment determined for the hospital, in accordance with paragraph (g)(1) of this section, adjusted by 1 plus the percent change in the aggregate amount of uncompensated care payments as estimated by CMS in accordance with paragraphs (g)(1)(i) and (ii) of this section between fiscal year 2022 and the applicable fiscal year. If the hospital did not qualify for an additional payment for uncompensated care under paragraph (g) of this section for fiscal year 2022, CMS uses the Factor 3 determined for the hospital under paragraph (g)(1)(iii)(C)(*9*) of this section to estimate the amount of the additional payment for uncompensated care that the hospital would have received in fiscal year 2022 if the hospital had qualified for an additional payment for uncompensated care under paragraph (g)(1) of this section for that fiscal year.

(ii) The additional payment for uncompensated care determined for the hospital for the applicable fiscal year, in accordance with paragraph (g)(1) of this section.

(4) If the base year amount under paragraph (h)(3)(i) of this section is equal to or lower than the additional payment for uncompensated care determined for the hospital for the applicable fiscal year in accordance with paragraph (g)(1) of this section, the hospital will not receive a supplemental payment under paragraph (h) of this section for that fiscal year.

* * * * *

§ 412.140 [Amended]

■ 7. Section 412.140 is amended in paragraph (d)(2)(ii) by removing the phrase ''at least 75 percent'' and adding in its place the phrase ''100 percent''.

■ 8. Section 412.168 is amended by—

■ a. Revising the section heading;

■ b. In paragraph (a), removing the phrase ''for the fiscal year 2022'' and adding in its place ''for each of fiscal years 2022 and 2023''; and

■ c. By adding paragraphs (g) through (k).

The revision and additions read as follows:

§ 412.168 Special rules for FY 2022 and FY 2023.

* * * * *

(g) CMS calculates a measure rate for all measures selected under § 412.164(a) for fiscal year 2023 but only applies § 412.165(a) to the measures included in the Clinical Outcomes Domain and the Efficiency and Cost Reduction Domain for that fiscal year, which are the following:

(1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (MORT–30–AMI).

(2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization (MORT–30–HF).

(3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN (updated cohort)).

(4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30–COPD).

(5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG).

(6) Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP–HIP–KNEE).

(7) Medicare Spending Per Beneficiary (MSPB)—Hospital.

(h) CMS calculates—

(1) A Clinical Outcomes Domain score for fiscal year 2023 for hospitals that report the minimum number of cases and measures with respect to the measures described in paragraphs (g)(1) through (6) of this section; and

(2) An Efficiency and Cost Reduction Domain score for fiscal year 2023 for hospitals that report the minimum number of cases with respect to the measure described in paragraph (g)(7) of this section.

(i) CMS does not award a Total Performance Score to any hospital for fiscal year 2023.

(j) The total amount available for value-based incentive payments for fiscal year 2023 is equal to the total amount of base-operating DRG payment reductions for that fiscal year, as estimated by the Secretary.

(k) CMS awards a value-based incentive payment percentage (as defined in § 412.160) for fiscal year 2023 to all hospitals to ensure that each hospital receives a value-based incentive payment amount equal to the amount of the reduction made to its base-operating DRG payment amounts.

■ 9. Section 412.273 is amended by revising paragraphs (d)(2) and (e) to read as follows:

§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination.

* * * * *

(d) * * *

(2) *Timing and process of cancellation request.* Cancellation requests must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB no later than the deadline

for submitting reclassification applications for the following fiscal year, as specified in § 412.256(a)(2).

* * * * *

(e) *Written request only.* (1) A request to withdraw an application must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB by all hospitals that are party to the application.

(2) A request to terminate an approved reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB by an individual hospital or by an individual hospital that is party to a group classification.

* * * * *

■ 10. Section 412.515 is revised to read as follows:

§ 412.515 LTC–DRG weighting factors.

(a) For each LTC–DRG, CMS assigns an appropriate weight that reflects the estimated relative cost of hospital resources used within that group compared to discharges classified within other groups.

(b)(1) Beginning FY 2023, each LTC–DRG weight is subject to a maximum 10 percent reduction as compared to the weight for the same LTC–DRG for the prior fiscal year, except as provided in paragraph (b)(2) of this section.

(2) The limitation described in paragraph (b)(1) of this section does not apply to LTC–DRGs with less than 25 applicable LTCH cases in the data used to determine the relative weights for the fiscal year.

■ 11. Section 412.525 is amended by revising paragraph (c)(1) to read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

* * * * *

(c) * * *

(1) The labor portion of a long-term care hospital's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index (established by CMS), which reflects the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined in accordance with the definitions set forth in § 412.503) of the hospital compared to the national average level of hospital wages and wage-related costs.

(i)(A) The appropriate wage index that is established by CMS is updated annually.

(B) Beginning in fiscal year 2023, if CMS determines that an LTCH's wage index value for a fiscal year would decrease by more than 5 percent as compared to the LTCH's wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

(ii) The labor portion of a long-term care hospital's Federal prospective payment is established by CMS and is updated annually.

* * * * *

■ 12. Section 412.529 is amended by revising paragraphs (d)(4)(ii)(B) and (d)(4)(iii)(B) to read as follows:

§ 412.529 Special payment provision for short-stay outliers.

* * * * *

(d) * * *

(4) * * *

(ii) * * *

(B)(*1*) Is adjusted for different area wage levels based on the geographic classifications set forth at § 412.503 and the applicable hospital inpatient prospective payment system (IPPS) labor-related share, using the applicable hospital inpatient prospective payment system wage index value for nonreclassified hospitals (an LTCH's applicable IPPS wage index).

(*2*) Beginning in fiscal year 2023, if CMS determines that an LTCH's applicable IPPS wage index value for a fiscal year would decrease by more than 5 percent as compared to the LTCH's applicable IPPS wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

(*3*) For LTCHs located in Alaska and Hawaii, the amount specified in paragraph (d)(4)(ii) of this section is also adjusted by the applicable hospital inpatient prospective payment system cost of living adjustment factors.

* * * * *

(iii) * * *

(B)(*1*) Is adjusted for the applicable geographic adjustment factors, including local cost variation based on the geographic classifications set forth at § 412.503 and the applicable full hospital inpatient prospective payment system (IPPS) wage index value for nonreclassified hospitals (an LTCH's applicable IPPS wage index) and applicable cost of living adjustment factors for LTCHs in Alaska and Hawaii.

(*2*) Beginning in fiscal year 2023, if CMS determines that an LTCH's applicable IPPS wage index value for a fiscal year would decrease by more than 5 percent as compared to the LTCH's applicable IPPS wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 13. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 14. Section 413.75 is amended in paragraph (b) by adding in alphabetical order the definitions of ''Rural track Medicare GME affiliated group'' and ''Rural track Medicare GME affiliation agreement'' to read as follows:

§ 413.75 Direct GME payments: General requirements.

* * * * *

(b) * * *

Rural track Medicare GME affiliated group means an urban hospital and a rural hospital that—

(i) Participate in a rural track program defined in this paragraph (b);

(ii) Have rural track FTE limitations in effect prior to October 1, 2022; and

(iii) Comply with the regulations at § 413.79(f)(1) through (6) for Medicare GME affiliated groups.

Rural track Medicare GME affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in a rural track Medicare GME affiliated group, as defined in this paragraph (b), that specifies all of the following:

(i) A statement attesting that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program.

(ii) The term of the rural track Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year.

(iii) Each participating hospital's direct and indirect GME rural track FTE limitations in effect prior to the rural track Medicare GME affiliation.

(iv) The total adjustment to each hospital's rural track FTE limitations in each year that the rural track Medicare GME affiliation agreement is in effect, for both direct GME and indirect medical education (IME), that reflects a positive adjustment to one hospital's direct and indirect rural track FTE limitations that is offset by a negative adjustment to the other hospital's (or

hospitals') direct and indirect rural track FTE limitations of at least the same amount.

(v) The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the rural track Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's rural track FTE limitations (in accordance with paragraph (iii) of this definition).

(vi) The names of the participating hospitals and their Medicare provider numbers.

* * * * *

■ 15. Section 413.79 is amended by revising paragraphs (c)(2)(iii) and adding a sentence at the end of paragraph (d)(3) to read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(c) * * *

(2) * * *

(iii) Effective for cost reporting periods beginning on or after October 1, 2001, if the hospital's unweighted number of FTE residents exceeds the limit described in this section, and the number of weighted FTE residents in accordance with paragraph (b) of this section also exceeds that limit, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the limit. If the number of FTE residents weighted in accordance with paragraph (b) of this section does not exceed that limit, then the allowable weighted FTE count is the actual weighted FTE count.

* * * * *

(d) * * *

(3) * * * For cost reporting periods beginning on or after October 1, 2001, the hospital's weighted FTE counts for the preceding two cost reporting periods are calculated in accordance with the payment formula in paragraph (c)(2)(iii) of this section.

■ 16. Subpart F is amended by adding § 413.99 to read as follows:

§ 413.99 Qualified and Non-Qualified Deferred Compensation Plans.

(a) *Statutory basis, scope, and definitions*—(1) *Basis.* All payments to providers of services must be based on the reasonable cost of services covered under Title XVIII in accordance with section 1861(v) of the Act and the regulations in this part.

(2) *Scope.* This section and § 413.100(c)(2)(vii) apply to Medicare's treatment of the costs incurred for Qualified and Non-Qualified Deferred Compensation Plans.

(3) *Definitions.* As used in this section the following definitions apply:

Deferred Compensation means remuneration currently earned by an employee that is not received until a subsequent period, usually after retirement.

Employee Retirement Income Security Act of 1974 (ERISA) is a Federal law that sets standards of protection for individuals in most voluntarily established, private-sector retirement plans. The law is set forth in Title 29, Chapter 18 of the U.S. Code.

Funded Plan means a plan in which assets have been irrevocably and unconditionally set aside with a third party for the payment of plan benefits (for example, in a trust or escrow account), and those assets are beyond the reach of the employer or its general creditors.

Non-Qualified Deferred Compensation Plan (NQDC) means an elective or non-elective plan, agreement, method, or arrangement between an employer and an employee to pay the employee compensation in the future. In comparison with qualified plans, nonqualified plans do not provide employers and employees with the tax benefits associated with qualified plans because NQDC plans do not satisfy all the requirements of 26 U.S.C. 401(a).

Non-Qualified Defined Benefit Plan (NQDB) means a type of NQDC that is established and maintained by the employer primarily to provide definitely determinable benefits to its employees usually over a period of years, or for life, after retirement. Such benefits are generally measured by, and based on, such factors as age of employees, years of service, and compensation received by the employees.

Pension Benefit Guaranty Corporation (PBGC) is a Federal agency created by ERISA to protect benefits in private-sector QDBP plans described in section 3(35) of ERISA.

Qualified Defined Benefit Plan (QDBP) means a type of Qualified Deferred Compensation Plan that is established and maintained by the employer primarily to provide definitely determinable benefits to its employees usually over a period of years, or for life, after retirement. Such benefits are generally measured by, and based on, such factors as age of employees, years of service, and compensation received by the employees. A QDBP meets the applicable requirements of ERISA, as amended, and the requirements for a QDBP under 26 U.S.C. 401(a). Under a qualified plan, employers are entitled to deduct expenses in the year the employer makes contributions even though employees will not recognize income until the receipt of distributions.

Qualified Defined Contribution or Individual Account Plan (QDCP) means a type of Deferred Compensation Plan in which the employee, the employer, or both, contribute to an employee's individual account under the plan. The amount in the account at distribution includes the contributions and investment gains or losses, minus any investment and administrative fees. The value of the account changes based on contributions and the value and performance of the investments. A QDCP meets the applicable requirements of ERISA, as amended, and the requirements set forth in 26 U.S.C. 401(a), and, if applicable 26 U.S.C. 401(k).

Unfunded Plan means a plan in which benefits are supported by assets that have not been set aside (that is, a ''pay as you go'' plan), or by assets that have been set aside, but remain subject to the claims of the employer's general creditors.

(b) *Principle requirements*—(1) *General.* Deferred Compensation contributions or payments must be made by a provider of services, or an employee of the provider of services, to a Qualified or Non-Qualified Deferred Compensation Plan, established and maintained by the provider of services to provide retirement income to employees or to result in the deferral of income by employees for periods extending to the termination of covered employment or beyond. Contributions or payments made by a provider of services for the benefit of its employees to a Qualified or Non-Qualified Deferred Compensation Plan are allowable, when, and to the extent that, such costs are actually incurred by the provider of services and found to be reasonable and necessary under the principles of reasonable cost.

(2) *Deferred Compensation for provider-based physicians services in a hospital or SNF.* Costs incurred by a hospital or SNF to fund a Qualified or Non-Qualified Deferred Compensation Plan for a provider-based physician must meet the following requirements to be allowable under the program:

(i) The allocation of physician compensation costs required under § 415.60 of this chapter does not attribute the provider-based physician's Deferred Compensation entirely to one

category of service and his current compensation to another.

(ii) Contributions or payments toward the Qualified or Non-Qualified Deferred Compensation Plan do not include any cost excluded from the definition of physician compensation at § 415.60(a) of this chapter.

(iii) The amount of Deferred Compensation does not exceed the amount specified in the agreement required by § 415.60(g) of this chapter.

(iv) An arrangement between a physician and a provider of services under which the physician is reimbursed for patient charges, but the provider of services does the billing as a Deferred Compensation agreement, is not allowed.

(v) The costs incurred for physician guaranteed arrangements for hospital emergency room availability services, must meet the following additional requirements:

(A) The terms of both the guarantee arrangements and the Deferred Compensation Plan establish the amounts to be included at the beginning of the hospital's cost reporting period.

(B) The amount of Deferred Compensation is included in the guaranteed amount.

(C) The hospital contributes to the Deferred Compensation Plan from its own funds.

(D) The amount of Deferred Compensation that is allowable is limited to the amount by which the guarantee, including Deferred Compensation, exceeds the total billed by the hospital to all patients for the physician's patient care services.

(E) When the physician's charges to all patients equal or exceed the amount guaranteed by the hospital, the program does not recognize a Deferred Compensation contribution/payment.

(c) *Requirements for Non-Qualified and Qualified Deferred Compensation Plans*—(1) *NQDC requirements.* In order for contributions or payments by a provider of services to an NQDC as defined at paragraph (a)(3) of this section to be allowable under the program, the NQDC must meet the general requirements at paragraph (c)(1)(i) of this section, and it must either meet the requirements for a funded NQDC at paragraph (c)(1)(ii) of this section or the requirements for an unfunded NQDC at paragraph (c)(1)(iii) of this section, as applicable.

(i) *General requirements.* An NQDC must satisfy the requirements for document compliance and operational compliance set forth in 26 U.S.C. 409A.

(ii) *Funded NQDCs.* A funded NQDC must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(iii) *Unfunded NQDCs.* An NQDC that is unfunded must meet the definition of an Unfunded Plan in paragraph (a)(3) of this section, and there must be no constructive receipt of income for employees from a NQDC as a result of contributions made by a provider of services.

(2) *QDCP requirements.* A QDCP must meet the applicable requirements of ERISA, as amended, and the requirements set forth in 26 U.S.C. 401(a), and if applicable 26 U.S.C. 401(k). A QDCP must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(3) *QDBP requirements.* A QDBP must meet the applicable requirements of ERISA, as amended, and the requirements for a defined benefit plan under 26 U.S.C. 401(a). A QDBP must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(4) *NQDB requirements.* In order for contributions or payments by a provider of services to an NQDB as defined at paragraph (a)(3) of this section to be allowable under the program, the NQDB must meet the general requirements at paragraph (c)(4)(i) of this section, and it must either meet the requirements for a funded NQDB at paragraph (c)(4)(ii) of this section or the requirements for an unfunded NQDB at paragraph (c)(4)(iii) of this section, as applicable.

(i) *General requirements.* An NQDB must satisfy the requirements for document compliance set forth in 26 U.S.C. 409A and operational compliance set forth in 26 U.S.C. 409A(a).

(ii) *Funded NQDBs.* An NQDB that is funded must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(iii) *Unfunded NQDBs.* An NQDB that is unfunded must meet the definition of an Unfunded Plan in paragraph (a)(3) of this section, and there must be no constructive receipt of income for employees from a NQDB as a result of contributions made by a provider of services.

(5) *Funded Plan requirements*—(i) *Acceptable funding mechanism.* Both provider of services contributions and employee contributions must be used either to purchase an insured plan with a commercial insurance company, to establish a custodial bank account, or to establish a trust fund administered by a trustee.

(ii) *Life insurance contracts.* The purchase of an ordinary life insurance contract (for example, whole life, straight life, or other) is not a deferral of compensation and is not recognized as a funding mechanism, even where it is convertible at the normal retirement date specified in the policy to an annuity payable over the remaining life of the employee.

(iii) *Sole benefit of participating employees.* Regardless of the funding mechanism utilized, all provider of services and employee contributions to the fund established under the Deferred Compensation Plan and income therefrom must be used for the sole benefit of the participating employees.

(d) *Recognition of contributions or payments to Qualified and Non-Qualified Deferred Compensation Plans*—(1) *General rule.* Except as provided for in paragraph (c)(1)(iii) of this section with respect to QDBPs and funded NQDBs, contributions to Qualified Deferred Compensation Plans or payments to plan participants from Non-Qualified Deferred Compensation Plans are recognized as allowable costs in accordance with paragraph (c)(1)(i) of this section (in the case of Unfunded Plans) and paragraph (c)(1)(ii) of this section (in the case of Funded Plans).

(i) *Unfunded Plans.* Contributions or payments made to an unfunded Deferred Compensation Plans (including unfunded NQDBs) by a provider of services on behalf of its employees are included in allowable costs only during the cost reporting period in which an actual payment is made to the participating employees (or their beneficiaries) and only to the extent considered reasonable, in accordance with § 413.100(c)(2)(vii)(A).

(ii) *Funded Plans.* Reasonable provider of services payments made under funded Deferred Compensation Plans (specifically, funded Defined Contribution Plans, but excluding QDBPs and funded NQDBs) are included in allowable costs in accordance with § 413.100(c)(2)(vii)(B).

(iii) *Exception for QDBPs and funded NQDBs.* (A) QDBP and NQDB contributions are found to have been incurred only if paid directly to participants or beneficiaries under the terms of the plan or to the QDBP or NQDB.

(B) Payments to a QDBP or funded NQDB for a cost reporting period must be measured on a cash basis. A contribution or payment is deemed to occur on the date it is credited to the fund established for the QDBP or funded NQDB, or for provider of

services payments made directly to a plan participant or beneficiary, on the date the provider of services account is debited.

(C) Payments or contributions made to fully fund a terminating QDBP or funded NQDB are to be included as funding on the date they are paid. Excess assets withdrawn from a QDBP or funded NQDB are to be treated as negative contributions on the date that they are withdrawn.

(D) QDBP and funded NQDB annual allowable costs are computed as follows:

(*1*) QDBP and funded NQDB costs and limits are computed in accordance with § 413.100(c)(2)(vii)(D).

(*2*) For purposes of determining the QDBP or funded NQDB cost limit under § 413.100(c)(2)(vii)(D)(*2*), provider of services contribution payments for each applicable cost reporting period must be determined on a cash basis without regard to any limit determined for the period during which the contributions were made, and excluding any contributions deposited in a prior period and treated as carry forward contributions.

(*3*) The averaging period used to determine the QDBP or funded NQDB cost limit must be determined without regard to a provider of services period of participation in the Medicare program. Periods that are not Medicare cost reporting periods (for example, periods prior to the hospital's participation in the Medicare program) must be defined as consecutive 12-month periods ending immediately prior to the provider of services initial Medicare cost reporting period.

(*4*) The averaging period used to determine the QDBP or funded NQDB cost limit must exclude all periods ending prior to the initial effective date of the plan (or a predecessor plan in the case of a merger).

(*5*) In general, the current period defined benefit cost and limit is computed and applied separately for each QDBP or funded NQDB offered by a provider of services. In the case of a plan merger, the contributions or payments made by a provider of services to a predecessor QDBP or funded NQDB and reflected in the assets subsequently transferred to a successor plan are treated as contribution payments made to the successor plan.

(2) [Reserved]

(e) *Documentation requirements.* Documentation must be maintained by the provider of services in accordance with § 413.20 to substantiate the allowability of contributions or payments to Qualified and Non-Qualified Deferred Compensation Plan(s) that it has included in its cost reports.

(1) *Required documentation.* The provider of services must maintain and make available, upon request by the contractor or CMS, certain specified documentation, to substantiate the allowability of the contributions or payments to its Qualified or Non-Qualified Deferred Compensation Plan(s), or both:

(i) Documentation that demonstrates that the provider of services is in compliance with 26 U.S.C. 409A and 409A(a), and, if applicable, 26 U.S.C. 457.

(ii) Ledger accounts/account statements for each plan participant noting current year deferrals, distributions and loans, including any deferral election forms completed by employees, any change requests, and the approval of such requests.

(iii) Documentation that demonstrates the amount(s) and date(s) of actual contributions or payments made to the Qualified or Non-Qualified Deferred Compensation Plan during the current cost reporting period.

(iv) Schedule SB of Form 5500 (tri-agency form (Department of Labor (DOL), Internal Revenue Service (IRS), and PBGC) that plans file with the DOL's ''EFAST'' electronic filing system) for a QDBP for the current cost reporting period, or any applicable prior periods.

(v) In the case of a system-wide (multiple employer) plan, the home office shall identify the contributions attributed to each participating provider of services. If the costs included in the cost report for a period differ from the contributions made during the reporting period (that is, as a result of carry forward contributions), the provider of services must also have data available to track and reconcile the difference.

(2) *Additional documentation.* The following additional documentation must be made available, upon request by the contractor or CMS, to substantiate the allowability of the payments/contributions by a provider of services to a Qualified or Non-Qualified Deferred Compensation Plan:

(i) The plan document, the trust document and all amendments related to the current cost reporting period.

(ii) If applicable, any Form 5330, Return of Excise Taxes Related to Employee Benefit Plans, for the cost reporting period.

(iii)(A) Supporting documents for all plan assets and liabilities, such as broker's statements, bank statements, insurance contracts, loan documents, deeds, etc.

(B) Verification of how assets are valued.

(iv)(A) Trustee or administrator reports.

(B) Ledgers.

(C) Journals.

(D) Trustee, administrator, and investment committee minutes.

(E) Certified audit report and other financial reports for the trust.

(F) Any other financial reports, including receipt and disbursement statements, a detailed income statement, and a detailed balance sheet.

(v) For each covered QDBP, documentation of the certified premium information and payments to the PBGC.

(f) *Administrative and other costs associated with Deferred Compensation Plans.* The provider of services shall file a cost report required under §§ 413.20 and 413.24(f) that is consistent with the policies set forth in this section.

(1) *Trustee and custodial fees.* Reasonable trustee or custodial fees, including PBGC premiums, paid by the provider of services are allowed as an administrative cost except where the plan provides that such fees are paid out of the corpus or earnings of the fund.

(2) *Vested benefits.* The forfeiture of an employee's benefits for cause (as defined in the plan) is recognized as an allowable cost provided that such forfeited amounts are used to reduce the provider of services contributions or payments to the plan during the cost reporting period in which the forfeiture occurs.

(3) *Benefits to be paid.* If an employee terminates participation in the Deferred Compensation Plan before their rights are vested, the applicable non-vested contributions/payments cannot be applied to increase the benefits of the surviving participants. Instead the non-vested contributions or payments should be used to reduce the provider of services contributions or payments to the Deferred Compensation Plan, in the cost reporting period in which the employee terminated participation in the Deferred Compensation Plan. Otherwise, the contributions/payments made by the provider of services must be applied to reduce the subsequent contributions or payments to the Deferred Compensation Plan in the next cost reporting period. If subsequent provider of services contributions/payments to the Deferred Compensation Plan are not made, then the provider of services costs are reduced by the contractor to the extent of such non-vested funds.

(4) *DOL, IRS, or PBGC penalties.* If the provider of services is assessed an excise tax or other remedy by the DOL, IRS, or PBGC for failure to follow DOL,

IRS, or PBGC requirements under ERISA or any other penalty fee or penalty interest applicable to its Deferred Compensation Plan, the cost is unallowable in accordance with section 1861(v)(8) of the Act.

(5) *Loans made from a Deferred Compensation Plan.* A provider of services cannot make a loan to itself from a Deferred Compensation Plan where ERISA or IRS rules prohibit such a transaction, except where specifically excepted.

(6) *Termination/discontinuation of a Deferred Compensation Plan.* If the provider of services declines to vest its outstanding required contributions or payments (that is, matching or non-elective) to a Deferred Compensation Plan as a result of a termination in full or in part or a discontinuation of contributions or payments to a Deferred Compensation Plan, then the provider of services total outstanding required contributions or payments to the Deferred Compensation Plan during the cost reporting period wherein such termination is initiated cannot be included in the provider of services allowable cost for the cost reporting period in which the termination is initiated, nor any future period.

(7) *Required offset against interest expense.* Investment income earned on a Deferred Compensation Plan after its termination but prior to liquidation of the plan's assets and distribution to the provider of services must be offset against the provider of services allowable interest expense under § 413.153.

(8) *Treatment of residual assets following termination of a Funded Plan.* (i) Residual assets arising from the termination of a funded Deferred Compensation Plan must be recouped in the year of the plan termination only against the cost center(s) in which the provider of services reported its plan contributions or payments, usually the administrative and general cost center.

(ii) Residual assets exceeding the amount in the administrative and general (or other) cost center are not further offset in the current or subsequent years.

(iii) The Medicare share of the reversion is based on the Medicare utilization rate in the year the reversion occurs (or the year the actuarial surplus is determined), and not Medicare's utilization in the years the contributions to the plan were made.

(g) *Treatment of costs associated with the PBGC.* Costs associated with the requirements set forth in ERISA and by the PBGC and incurred by a provider of services who sponsors a QDBP are allowable or unallowable under the program as provided for in this paragraph (g).

(1) *Costs paid out of the plan trust.* PBGC premiums and costs paid out of the corpus or earnings of the trust are included in the contributions allowed under paragraph (d)(1)(iii)(A) of this section, and are not allowable as separate costs.

(2) *Premium payments for single- and multi-employer plans.* The amount of PBGC premiums paid for basic benefits (flat rate or variable, excluding amounts paid out of the corpus or earnings of the trust) by a provider of services who sponsors a QDBP are allowable under the program.

(3) *Liability for missing participants or beneficiaries.* The total amount paid to the PBGC by a provider of services who sponsors a QDBP (excluding amounts paid out of the corpus or earnings of the trust) of the benefit transfer amount (as described in 29 CFR 4050.103(d)) for all missing participants or beneficiaries of the QDBP, is allowable under the program.

(4) *Plan termination due to distress.* For a defined benefit plan that terminated with insufficient assets to pay all of the plan benefits, which resulted in the PBGC making payment of vested benefits up to limits defined by law in accordance with 29 CFR part 4022, such amounts contributed to the QDBP by the provider of services who sponsors the QDBP are allowable. Benefits paid to the participants and beneficiaries of the QDBP by the PBGC are unallowable.

(5) *Restored plan payments.* If the PBGC issues or has issued a plan restoration order as described in 29 CFR part 4047, the amounts that the provider of services repays to the PBGC for guaranteed benefits and related expenses under the plan while the plan was in terminated status, and any administrative costs assessed by the PBGC, excluding penalties, are allowable.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 17. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 18. Section 482.42 is amended by revising paragraphs (e) and (f) to read as follows:

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(e) *COVID–19 reporting.* (1) During the Public Health Emergency, as defined in § 400.200 of this chapter, the hospital must report information in accordance with a frequency as specified by the Secretary on COVID–19 in a standardized format specified by the Secretary. This report must include, but not be limited to, the following data elements:

(i) The hospital's current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital under the authority and direction of the Secretary.

(ii) The hospital's current usage rate for any COVID–19-related therapeutics that have been distributed and delivered to the hospital under the authority and direction of the Secretary.

(2) Beginning at the conclusion of the COVID–19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (e)(2), the hospital must electronically report information about COVID–19 in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed COVID–19 infections among patients.

(ii) Total deaths among patients.

(iii) Personal protective equipment and testing supplies.

(iv) Ventilator use, capacity, and supplies.

(v) Total bed and intensive care unit bed census and capacity.

(vi) Staffing shortages.

(vii) COVID–19 vaccine administration data of patients and staff.

(viii) Relevant therapeutic inventories or usage, or both.

(f) *Standard: Reporting of acute respiratory illness, including seasonal influenza virus, influenza-like illness, and severe acute respiratory infection.* (1) During the Public Health Emergency, as defined in § 400.200 of this chapter, the hospital must report information, in accordance with a frequency as specified by the Secretary, on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) in a standardized format specified by the Secretary.

(2) Beginning at the conclusion of the COVID–19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (f)(2), the hospital must electronically report information about seasonal influenza in a standardized format specified by the Secretary. To the

extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed influenza infections among patients.

(ii) Total deaths among patients.

(ii) Confirmed co-morbid influenza and COVID–19 infections among patients.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 19. The authority citation for part 485 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

■ 20. Section 485.640 is amended by revising paragraphs (d) and (e) to read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(d) *COVID–19 reporting.* (1) During the Public Health Emergency, as defined in § 400.200 of this chapter, the CAH must report information in accordance with a frequency as specified by the Secretary on COVID–19 in a standardized format specified by the Secretary. This report must include, but not be limited to, the following data elements:

(i) The CAH's current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary; and

(ii) The CAH's current usage rate for any COVID–19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary.

(2) Beginning at the conclusion of the COVID–19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (d)(2), the CAH must electronically report information about COVID–19 in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed COVID–19 infections among patients.

(ii) Total deaths among patients.

(iii) Personal protective equipment and testing supplies.

(iv) Ventilator use, capacity, and supplies.

(v) Total bed and intensive care unit bed census and capacity.

(vi) Staffing shortages.

(vii) COVID–19 vaccine administration data of patients and staff.

(viii) Relevant therapeutic inventories or usage, or both.

(e) *Standard: Reporting of acute respiratory illness, including seasonal influenza virus, influenza-like illness, and severe acute respiratory infection.* (1) During the Public Health Emergency, as defined in § 400.200 of this chapter, the CAH must report information, in accordance with a frequency as specified by the Secretary, on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) in a standardized format specified by the Secretary.

(2) Beginning at the conclusion of the COVID–19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (e)(2), the CAH must electronically report information about seasonal influenza in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed influenza infections among patients.

(ii) Total deaths among patients.

(iii) Confirmed co-morbid influenza and COVID–19 infections among patients.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 21. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 22. Section § 495.24 is amended—

■ a. In the introductory text, by revising the last sentence and adding a new sentence at the end of the paragraph;

■ b. In paragraph (e), in the paragraph heading by removing the phrase ''for 2019 and subsequent years'' and adding in its place the phrase ''for 2019 through 2022.'';

■ c. In paragraph (e)(1)(i)(C), by removing the phrase ''In 2022 and subsequent years, earn'' and adding in its place the phrase ''In 2022, earn'';

■ d. In paragraph (e)(4)(ii), by removing the phrase ''In 2022 and subsequent years'' and adding in its place the phrase ''In 2022'';

■ e. In paragraph (e)(5)(ii)(B), by removing the phrase ''In 2020 and subsequent years'' and adding in its place the phrase ''In 2020 through 2022'';

■ f. In paragraph (e)(5)(iii)(A), by removing the phrase ''in CY 2019 and subsequent years'' and adding in its place ''in CY 2019 through CY 2022.'';

■ g. In paragraph (e)(5)(v), by removing the phrase ''Beginning with the EHR reporting period in CY 2019'' and adding in its place ''For the EHR reporting periods in CY 2019 through CY 2022'';

■ h. In paragraph (e)(7)(ii) introductory text, by removing the phrase ''beginning in CY 2019'' and adding in its place the phrase ''for CY 2019 through CY 2022'';

■ i. In paragraph (e)(8)(ii), by removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022'';

■ j. In paragraph (e)(8)(ii)(A), by removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022'';

■ k. In paragraphs (e)(8)(iii) introductory text, by removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022'';

■ l. In paragraph (e)(8)(iii)(A)(*2*), by removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022'';

■ m. In paragraph (e)(8)(iii)(D)(*2*), by removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022'';

■ n. In paragraph (e)(8)(iii)(E)(*2*), by removing the phrase ''For CY 2022 and subsequent years'' and adding in its place ''For CY 2022''; and

■ o. Adding paragraph (f).

The revision and addition read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * The criteria specified in *paragraph (e)* of this section are applicable for eligible hospitals and CAHs attesting to CMS for 2019 through 2022. The criteria specified in paragraph (f) of this section are applicable for eligible hospitals and CAHs attesting to CMS for 2023 and subsequent years

* * * * *

(f) *Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2023 and subsequent years.* (1) *General rule.* (i) Except as specified in paragraph (f)(2) of this section, eligible hospitals and CAHs must do all of the following as part of meeting the definition of a meaningful EHR user under § 495.4:

(A) Meet all objectives and associated measures selected by CMS under section 1886(n)(3) of the Act for an EHR reporting period.

(B) In 2023 and subsequent years, earn a total score of at least 60 points.

(ii) The numerator and denominator of the measures increment based on actions occurring during the EHR reporting period selected by the eligible hospital or CAH, unless otherwise indicated.

(2) *Exclusion for nonapplicable measures.* (i) *Exclusion of a particular measure.* An eligible hospital or CAH may exclude a particular measure that includes an option for exclusion if the eligible hospital or CAH meets the following requirements:

(A) Meets the criteria in the applicable measure that would permit the exclusion.

(B) Attests to the exclusion.

(ii) *Distribution of points for nonapplicable measures.* For eligible hospitals or CAHs that claim such exclusion, the points assigned to the excluded measure are distributed to other measures as specified by CMS for an EHR reporting period.

Dated: July 27, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2022, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2022

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2023 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2023. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2022. In addition, we are setting forth a description of the methods and data we used to determine the LTCH PPS standard Federal payment rate that will be applicable to Medicare LTCHs for FY 2023.

In general, except for SCHs, for FY 2023, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation. Under current law, the MDH program is effective for discharges on or before September 30, 2022. Therefore, under current law, the MDH program will expire at the end of FY 2022.

Sole Community Hospitals (SCHs) are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (including, as discussed in section IV.G. of the preamble of this final rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

As discussed in section V.A.2. of the preamble of this final rule, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. In general, Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update. Accordingly, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2023. In section III. of this Addendum, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2023. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2023. In section V. of this Addendum, we discuss policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2023. The tables to which we refer in the preamble of this final rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2023

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. In this section, we discuss the factors we are using for determining the proposed prospective payment rates for FY 2023. In summary, the standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2023, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.A. of the preamble of this final rule for a complete discussion on the FY 2023 inpatient hospital update. The table that follows shows these four scenarios:

FY 2023 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS				
FY 2023	**Hospital Submitted Quality Data and is a Meaningful EHR User**	**Hospital Submitted Quality Data and is NOT a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User**
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-1.025	-1.025
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-3.075	0	-3.075
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.3	-0.3	-0.3	-0.3
Applicable Percentage Increase Applied to Standardized Amount	**3.8**	**0.725**	**2.775**	**-0.3**

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user (as defined in section 1886(n)(3) of the Act) and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket update, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674). The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2023 and subsequent fiscal years.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to the standardized amount to ensure budget neutrality for our permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year beginning FY 2023, as discussed in section II.E.2.d. of the preamble of this final rule, consistent with our current methodology for implementing DRG recalibration and reclassification budget neutrality under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005)). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2022 budget neutrality factor and applying a revised factor.
- A positive adjustment of 0.5 percent in FYs 2019 through 2023 as required under section 414 of the MACRA.
- An adjustment to the standardized amount to implement in a budget neutral manner the increase in the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (as described in section III.N. of the preamble of this final rule).
- An adjustment to the standardized amount to implement in a budget neutral manner our permanent wage index cap policy, as discussed in section III. N of the preamble of this final rule.
- An adjustment to ensure the effects of the Rural Community Hospital Demonstration program required under section 410A of Public Law 108–173 (as amended by sections 3123 and 10313 of Public Law 111–148; section 15003 of Public Law 114–255; and Division CC, section 128 of Public Law 116–260, which extended the program), are budget neutral, as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment to remove the FY 2022 outlier offset and apply an offset for FY 2023, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2023, consistent with current law, we are applying the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are applying a uniform, national budget neutrality adjustment to the FY 2023 wage index for the rural floor.

For FY 2023, we proposed to not remove the Stem Cell Acquisition Budget Neutrality Factor from the prior year's standardized amount and to not apply a new factor. If we removed the prior year's adjustment, we would not satisfy budget neutrality. We believe this approach ensures the effects of the reasonable cost-based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) are budget neutral as required under section 108 of Public Law 116–94. For a discussion of Stem Cell Acquisition Budget Neutrality Factor, we refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59032 and 59033). When cost report data regarding reasonable cost of acquisition become available, we intend to consider using that reasonable cost data in future rulemaking for budget neutrality.

We did not receive comments on stem cell acquisition budget neutrality. We are finalizing as proposed without modification.

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983, interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost

variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2023, as we proposed, we are continuing to use the national labor-related and nonlabor-related shares (which are based on the 2018-based IPPS market basket) that were used in FY 2022. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2023, as discussed in section III.M. of the preamble of this final rule, as we proposed, we are using a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, as proposed, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this final rule and are available via the internet on the CMS website.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, as proposed, we are calculating the FY 2023 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, we are using the 2018-based IPPS operating and capital market baskets for FY 2023. As discussed in section IV.B. of the preamble of this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are reducing the FY 2023 applicable percentage increase (which for this final rule is based on IGI's second quarter 2022 forecast of the 2018-based IPPS market basket) by the productivity adjustment, as discussed elsewhere in this final rule.

Based on IGI's second quarter 2022 forecast (as discussed in Appendix B of this final rule), the forecast of the IPPS market basket increase for FY 2023 for this final rule is 4.1 percent. As discussed earlier, for FY 2023, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section V.B. of the preamble of this final rule for a complete discussion on the FY 2023 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four possible applicable percentage increases that would be applied to update the national standardized amount. The standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2023 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2023 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this final rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the FY 2023 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs at the time of this final rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS excluded-cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- As in the past, we are adjusting the FY 2023 standardized amount to remove the effects of the FY 2022 geographic reclassifications and outlier payments before applying the FY 2023 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2023 payment policies.
- We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We are removing organ acquisition charges, except for cases that group to MS–DRG 018, from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS. Revenue centers 081X–089X are typically excluded from ratesetting. However, we are not removing revenue center 891 charges from MS–DRG 018 claims during ratesetting, because those revenue 891 charges were included in the relative weight calculation for MS–DRG 018, which is consistent with the policy finalized in FY 2021 final rule (85 FR 58600). We note that a new MedPAR variable for revenue code 891 charges was introduced in April 2020.

• For FY 2023, we are continuing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).

• The participation of hospitals under the BPCI (Bundled Payments for Care Improvement) Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced model in one of two capacities: as a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals would continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/bpci-advanced/*.

For FY 2023, consistent with how we treated hospitals that participated in the BPCI Advanced Model in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59029 and 59030), as we proposed, we are including all applicable data from subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act. For the same reasons, as we proposed, we included all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2023, we are continuing to apply a proxy based on the prior fiscal year hospital readmissions payment adjustment (for FY 2023 this would be FY 2022 final adjustment factors from Table 15 of the FY 2022 IPPS/LTCH PPS final rule) and a proxy based on the prior fiscal year hospital VBP payment adjustment (for FY 2023, this proxy would be an adjustment factor of 1 to reflect our policy for the FY 2022 program year to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount) on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are applying a proxy readmissions payment adjustment factor from the prior final rule and a proxy hospital VBP payment adjustment factor from the prior final rule on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, would be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2023 (as we did for the last 9 fiscal years), as we proposed, we are including estimated empirically justified Medicare DSH payments that would be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we considered estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.G. of the preamble to this final rule and later in this section, we are continuing to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are including estimated uncompensated care payments in this comparison.

• As we proposed, we included an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2023. Similar to FY 2022, we are including this adjustment based on data on the prior year's performance. Payments for hospitals will be estimated based on the applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2023.

• In our determination of all budget neutrality factors described in section II.A.4. of this Addendum, we used transfer-adjusted discharges. Specifically, we calculated the transfer-adjusted discharges using the statutory expansion of the postacute care transfer policy to include discharges to hospice care by a hospice program as discussed in section IV.A.2. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 45239 through 42342).

We note that prior to FY 2020, the Rural Community Hospital (RCH) Demonstration budget neutrality factor was typically applied to the standardized amount after all wage index and other budget neutrality factors were applied. In the past we completed all the wage index budget neutrality factors and then applied the RCH Demonstration budget neutrality factor. Beginning with FY 2020, we finalized and implemented additional policies in a budget neutral manner such as the increase in the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals and the transitional wage indexes. When these new policies were implemented beginning with FY 2020, the associated budget neutrality adjustments were applied to the standardized amount after the RCH Demonstration budget neutrality factor was applied. Taking into consideration that we are placing a permanent cap on wage index decreases beginning FY 2023, we believe the RCH Demonstration budget neutrality factor should revert to the order prior to FY 2020 and be applied after all wage index and other budget neutrality adjustments. Therefore, in the FY 2023 IPPS/LTCH proposed rule (87 FR 28659), beginning in FY 2023 we proposed to change the ordering of budget

neutrality factors with the RCH Demonstration budget neutrality factor applied after all wage index and other budget neutrality factors. We stated that we believe this re-ordering of applying the RCH Demonstration budget neutrality factor after all wage index and other budget neutrality factors will have a minimal impact and minor interactive affects.

We received no comments on our proposal and therefore are finalizing as proposed without modification to change the ordering of budget neutrality factors with the RCH Demonstration budget neutrality factor applied after all wage index and other budget neutrality factors.

a. Reclassification and Recalibration of MS–DRG Relative Weights Before Cap

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.E of this final rule, we are determining the MS DRG relative weights for FY 2023 by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data. We refer the reader to section II.E.2.c for complete details. As discussed in section II.E. of the preamble of this final rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For this FY 2023 final rule, as we proposed, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2021 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2022 labor-related share percentages, the FY 2022 relative weights, and the FY 2022 pre-reclassified wage data, and applied the estimated FY 2023 hospital readmissions payment adjustments and estimated FY 2023 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2022 labor-related share percentages, the FY 2023 relative weights before applying the 10-percent cap, and the FY 2022 pre-reclassified wage data, and applied the estimated FY 2023 hospital readmissions payment adjustments and estimated FY 2023 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the FY 2023 relative weights (before application of the 10-percent cap), consistent with our policy in section IV.I. of the preamble to this final rule, we applied the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2023 relative weights, we are applying the adjustor for certain MS–DRG 18 cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section IV.I. of the preamble of this final rule for a complete discussion on the adjustor for certain cases that group to MS–DRG 018 and to section II.E.2.b. of the preamble of this final rule, for a complete discussion of the adjustment to the FY 2023 relative weights to account for certain cases that group to MS–DRG 018.

Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, as we proposed, we are applying the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2022. Please see the table later in this section setting forth each of the FY 2023 budget neutrality factors.

b. Budget Neutrality Adjustment for Reclassification and Recalibration of MS–DRG Relative Weights With Cap

As discussed in section II.E.2.d of this final rule, as proposed we are establishing a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. As discussed in section II.E.2.d of this final rule, and consistent with our current methodology for implementing budget neutrality for MS–DRG reclassification and recalibration of the relative weights under section 1886(d)(4)(C)(iii) of the Act, we are applying a budget neutrality adjustment to the standardized amount for all hospitals so that this 10-percent cap on relative weight reductions does not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. We refer the reader to section II.E.2.d of this final rule for further discussion on our permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, including the budget neutrality adjustment to the standardized amount.

To calculate this budget neutrality adjustment factor for FY 2023, we used FY 2021 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2022 labor-related share percentages, the FY 2023 relative weights before applying the 10-percent cap, and the FY 2022 pre-reclassified wage data, and applied the estimated FY 2023 hospital readmissions payment adjustments and estimated FY 2023 hospital VBP payment adjustments.
- Aggregate payments using the FY 2022 labor-related share percentages, the FY 2023 relative weights with the 10-percent cap, and the FY 2022 pre-reclassified wage data, and applied the estimated FY 2023 hospital readmissions payment adjustments and estimated FY 2023 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the FY 2023 relative weights, consistent with our policy in section IV.I. of the preamble to this final rule, we applied the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2023 relative weights, we are applying the adjustor for certain MS–DRG 18 cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section IV.I. of the preamble of this final rule for a complete discussion on the adjustor for certain cases that group to MS–DRG 018 and to section II.E.2.b. of the preamble of this final rule, for a complete discussion of the adjustment to the FY 2023 relative weights to account for certain cases that group to MS–DRG 018.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor before the cap (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2022 to FY 2023. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are applying this budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2022. Please see the table later in this section setting forth each of the FY 2023 budget neutrality factors.

c. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent.

Consistent with current policy, for FY 2023, as we proposed, we are adjusting 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this final rule.

To compute a budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2021 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2023 relative weights and the FY 2022 pre-reclassified wage indexes, applied the FY 2022 labor-related share of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the FY 2023 hospital readmissions payment adjustment and the estimated FY 2023 hospital VBP payment adjustment.
- Aggregate payments using the FY 2023 relative weights and the FY 2023 pre-reclassified wage indexes, applied the labor-related share for FY 2023 of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same FY 2023 hospital readmissions payment adjustments and estimated FY 2023 hospital VBP payment adjustments applied previously.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor before the cap (derived in the first step) and the 10-percent cap on relative weight reductions adjustment factor (derived from the second step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2022 to FY 2023. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the FY 2023 budget neutrality factors.

d. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions.

As discussed in section III.G.1. of the preamble of this final rule, for FY 2023 and subsequent years, we are finalizing a policy to include the wage data of hospitals that have reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) and have no additional form of reclassification (MGCRB or Lugar) in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) of the Act shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality adjustment factor for FY 2023, we used FY 2021 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2023 labor-related share percentage, the FY 2023 relative weights, and the FY 2023 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments.
- Aggregate payments using the FY 2023 labor-related share percentage, the FY 2023 relative weights, and the FY 2023 wage data after such reclassifications, and applied the same estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this final rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks for FY 2023, and applies the policies explained in section III. of the preamble of this final rule. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the FY 2023 budget neutrality factors.

The FY 2023 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2022 budget neutrality adjustment factor. We note that the FY 2023 budget neutrality adjustment reflects FY 2023 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this final rule.

e. Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) is equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this final rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2023, as we proposed, we calculated a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2023 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the FY 2023 rural Puerto Rico wage index is calculated based on the average of the FY 2023 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA 41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

We also note, as discussed in section III.G.1. of the preamble of this final rule, based on the district court's decision in *Citrus* and the comments we received, we are not finalizing our rural floor wage index policy as proposed, which would have excluded § 412.103 hospitals from the calculation of the rural floor and from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. Rather, we are finalizing a policy that calculates the rural floor as it was calculated before FY 2020. For FY 2023 and subsequent years, we are finalizing a policy to include the wage data of hospitals that have reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) and have no additional form of reclassification (MGCRB or Lugar) in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

To calculate the national rural floor budget neutrality adjustment factor, we used FY 2021 discharge data to simulate payments, and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the rural floor.
- National simulated payments with the rural floor.

Based on this comparison, we determined a national rural floor budget neutrality adjustment factor. The national adjustment was applied to the national wage indexes to produce rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the FY 2023 budget neutrality factors.

As further discussed in section III.G.2. of the preamble of this final rule, we note that section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021 amended section

1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index (or imputed floor) for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Unlike the imputed floor that was in effect from FY 2005 through FY 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In the past, we budget neutralized the estimated increase in payments each year resulting from the imputed floor that was in effect from FY 2005 through FY 2018. For FY 2022 and subsequent years, in applying the imputed floor required under section 1886(d)(3)(E)(iv) of the Act, we are applying the imputed floor after the application of the rural floor and applying no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor. We refer the reader to section III.G.2. of the preamble of this final rule for a complete discussion regarding the imputed floor.

f. Continuation of the Low Wage Index Hospital Policy—Budget Neutrality Adjustment

As discussed in section III.G.3. of the preamble of this final rule, we are continuing for FY 2023 the wage index policy finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (the low wage index hospital policy). As discussed in section III.G.3. of this final rule, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act, we are making a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for hospitals with a wage index below the 25th percentile wage index, is implemented in a budget neutral manner.

To calculate this budget neutrality adjustment factor for FY 2023, we used FY 2021 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2023 labor-related share percentage, the FY 2023 relative weights, and the FY 2023 wage index for each hospital before adjusting the wage indexes under the low wage index hospital policy, and applied the estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section.
- Aggregate payments using the FY 2023 labor-related share percentage, the FY 2023 relative weights, and the FY 2023 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the same estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments applied previously, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section.

This FY 2023 budget neutrality adjustment factor was applied to the standardized amount.

g. Permanent Cap Policy for the Wage Index—Budget Neutrality Adjustment

As noted previously, in section III.N. of the preamble of this final rule, for FY 2023 and subsequent years, we are finalizing as proposed to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. In section III.N.2. of this final rule, we are also applying this wage index cap policy in a budget neutral manner through an adjustment to the standardized amount to ensure that estimated aggregate payments under our wage index cap policy for hospitals that will have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent will equal what estimated aggregate payments would have been without the wage index cap policy. We refer readers to sections III.N.1 and III.N.2 of the preamble of this final rule for a complete discussion regarding this policy.

To calculate a wage index cap budget neutrality adjustment factor for FY 2023, we used FY 2021 discharge data to simulate payments and compared the following:

- Aggregate payments without the 5-percent cap using the FY 2023 labor-related share percentages, the FY 2023 relative weights, the FY 2023 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy with the associated budget neutrality adjustment to the standardized amount, and applied the estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section.
- Aggregate payments with the 5-percent cap using the FY 2023 labor-related share percentages, the FY 2023 relative weights, the FY 2023 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy with the associated budget neutrality adjustment to the standardized amount, and applied the same estimated FY 2023 hospital readmissions payment adjustments and the estimated FY 2023 hospital VBP payment adjustments applied previously, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section.

We note, Table 2 associated with this final rule contains the wage index by provider before and after applying the low wage index hospital policy and the cap.

h. Rural Community Hospital Demonstration Program Adjustment

In section V.K. of the preamble of this final rule, we discuss the Rural Community Hospital (RCH) Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Pub. L. 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed later in this section). Finally, Division CC, section 128(a) of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) again amended section 410A to require a 15-year extension period in place of the 10-year period. We make an adjustment to the standardized amount to ensure the effects of the RCH Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. We refer readers to section V.K. of the preamble of this final rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2023, based on the latest data for this final rule, the total amount that we will apply to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $108,439,824. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2023, we computed a factor for the Rural Community Hospital Demonstration budget neutrality adjustment that will be applied to the standardized amount. Please see the table later in this section for a summary of the FY 2023 budget neutrality factors. We refer readers to section V.K. of the preamble of this final rule for complete details regarding the calculation of the amount we will apply to make an adjustment to the standardized amounts.

The following table is a summary of the FY 2023 budget neutrality factors, as discussed in the previous sections.

Summary of FY 2023 Budget Neutrality Factors	
MS-DRG Reclassification and Recalibration Budget Neutrality Factor	1.000509
Cap Policy MS-DRG Weights Budget Neutrality Factor	0.999764
Wage Index Budget Neutrality Factor	1.000968
Reclassification Budget Neutrality Factor	0.984399
*Rural Floor Budget Neutrality Factor	0.991909
Low Wage Index Hospital Policy Budget Neutrality Factor	0.998146
Cap Policy Wage Index Budget Neutrality Factor	0.999689
Rural Demonstration Budget Neutrality Factor	0.998935

*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

As discussed in section II.A. of this final rule, we are using the FY 2021 data for FY 2023 ratesetting, with certain modifications to our relative weight and outlier methodologies. As discussed elsewhere in this final rule and in this Addendum, we solicited comments on, as an alternative to our proposed approach, the use of the FY 2021 MedPAR claims for purposes of FY 2023 ratesetting without these proposed modifications to our usual methodologies. In order to facilitate comments on this alternative approach, we made available budget neutrality and other ratesetting adjustments calculated under this alternative approach, which can be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We refer the reader to section I.O. of Appendix A of this final rule for further discussion of the files that we made available with regard to our alternative approach.

i. Adjustment for FY 2023 Required Under Section 414 of Public Law 114–10 (MACRA)

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. (As noted in the FY 2018 IPPS/LTCH PPS proposed and final rules, section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted December 13, 2016, reduced the adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points.) Therefore, for FY 2023, we are implementing the required +0.5 percent adjustment to the standardized amount. This is a permanent adjustment to the payment rates.

j. Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' (As discussed later in this section, we are also including the supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals in the computation of the outlier fixed-loss cost threshold beginning in FY 2023.) To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2023 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. As discussed in the next section, for FY 2023, we are incorporating an estimate of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html*.

(1) Methodology To Incorporate an Estimate of Outlier Reconciliation in the FY 2023 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. We have instructed MACs to identify for CMS any instances where: (1) A hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual (available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) for complete details regarding outlier reconciliation. The regulation at § 412.84(m) further states that at the time of any outlier reconciliation under § 412.84(i)(4), outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Section 20.1.2.6 of Chapter 3 of the Medicare Claims Processing Manual contains instructions on how to assess the time value of money for reconciled outlier amounts.

If the operating CCR of a hospital subject to outlier reconciliation is lower at cost report settlement compared to the operating CCR used for payment, the hospital would owe CMS money because it received an outlier overpayment at the time of claim payment. Conversely, if the operating CCR increases at cost report settlement compared to the operating CCR used for payment, CMS would owe the hospital money because the hospital outlier payments were underpaid.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42635), we finalized a methodology to incorporate outlier reconciliation in the FY 2020 outlier fixed

loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the methodology addresses stakeholder's concerns on the impact of outlier reconciliation on the modeling of the outlier threshold. For a detailed discussion of additional background regarding outlier reconciliation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule.

(a) Incorporating a Projection of Outlier Payment Reconciliations for the FY 2023 Outlier Threshold Calculation

Based on the methodology finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625), for FY 2023, as we proposed, we are continuing to incorporate outlier reconciliation in the FY 2023 outlier fixed loss cost threshold.

As discussed in the FY 2020 IPPS/LTCH PPS final rule, for FY 2020, we used the historical outlier reconciliation amounts from the FY 2014 cost reports (cost reports with a begin date on or after October 1, 2013, and on or before September 30, 2014), which we believed would provide the most recent and complete available data to project the estimate of outlier reconciliation. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625) for a discussion on the use of the FY 2014 cost report data for purposes of projecting outlier payment reconciliations for the FY 2020 outlier threshold calculation. For FYs 2021 and 2022, we applied the same methodology finalized in FY 2020, using the historical outlier reconciliation amounts from the FY 2015 cost reports (cost reports with a begin date on or after October 1, 2014, and on or before September 30, 2015) and the FY 2016 cost reports (cost reports with a begin date on or after October 1, 2015, and on or before September 30, 2016), respectively.

Similar to the FY 2022 methodology, in this final rule, we are determining a projection of outlier payment reconciliations for the FY 2023 outlier threshold calculation, by advancing the methodology by 1 year. Specifically, we are using FY 2017 cost reports (cost reports with a begin date on or after October 1, 2016, and on or before September 30, 2017).

For FY 2023, as we proposed, we are using the same methodology from FY 2020 to incorporate a projection of operating outlier payment reconciliations for the FY 2023 outlier threshold calculation. The following steps are the same as those finalized in the FY 2020 final rule but with updated data for FY 2023:

Step 1.—Use the Federal FY 2017 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude sole community hospitals (SCHs) that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule.

Step 2.—Calculate the aggregate amount of historical total of operating outlier reconciliation dollars (Worksheet E, Part A, Line 2.01) using the Federal FY 2017 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total Federal operating payments using the Federal FY 2017 cost reports from Step 1. The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Line 2 and Line 2.02), and the outlier reconciliation payments (Worksheet E, Part A, Line 2.01). We note that a negative amount on Worksheet E, Part A, Line 2.01 for outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments for FY 2017. This percentage amount would be used to adjust the outlier target for FY 2023 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we are targeting 5.1 percent minus the percentage determined in Step 4 in determining the outlier threshold. Using the FY 2017 cost reports based on the December 2021 HCRIS extract, because the aggregate outlier reconciliation dollars from Step 2 are negative, we are targeting an amount higher than 5.1 percent for outlier payments for FY 2023 under our methodology.

In the FY 2023 proposed rule, we used the December 2021 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2023 final rule, we proposed to use the latest quarterly HCRIS extract that is publicly available at the time of the development of that rule which, for FY 2023, would be the March 2022 extract. Similar to the FY 2022 final rule, we stated that we may also consider the use of more recent data that may become available for purposes of projecting the estimate of operating outlier reconciliation used in the calculation of the final FY 2023 outlier threshold.

In the FY 2023 proposed rule, based on the December 2021 HCRIS, 10 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $11,939,505 (Step 2). The total Federal operating payments based on the December 2021 HCRIS was $88,388,722,611 (Step 3). The ratio (Step 4) is a negative 0.013508 percent, which, when rounded to the second digit, is −0.01 percent. Therefore, for FY 2023, we proposed to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent − (−0.01 percent)].

When the percentage of operating outlier reconciliation dollars to total Federal operating payments rounds to a negative value (that is, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of the Addendum to the proposed rule, we provided the proposed FY 2023 outlier threshold as calculated for the proposed rule both with and without including this percentage estimate of operating outlier reconciliation.

As explained in the FY 2020 IPPS/LTCH PPS final rule, we finalized the continued use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. In the past, the outlier offset was six decimals because we targeted and set the threshold at 5.1 percent by adjusting the standardized amount by the outlier offset until operating outlier payments divided by total operating Federal payments plus operating outlier payments equaled approximately 5.1 percent (this approximation resulted in an offset beyond 3 decimals). However, under our methodology, we believe a 3-decimal offset of 0.949 reflecting 5.1 percent is appropriate rather than the unrounded 6-decimal offset that we have calculated for prior fiscal years. Specifically, as discussed in section II.A.5. of this Addendum, we proposed to determine an outlier adjustment by applying a factor to the standardized amount that accounts for the projected proportion of total estimated FY 2023 operating Federal payments paid as outliers. Our proposed modification to the outlier threshold methodology is designed to adjust the total estimated outlier payments for FY 2023 by incorporating the projection of negative outlier reconciliation. That is, under this proposal, total estimated outlier payments for FY 2023 would be the sum of the estimated FY 2023 outlier payments based on the claims data from the outlier model and the estimated FY 2023 total operating outlier reconciliation dollars. We stated that we believe the proposed methodology would more accurately estimate the outlier adjustment to the standardized amount by increasing the accuracy of the calculation of the total estimated FY 2023 operating Federal payments paid as outliers. In other words, the net effect of our proposal to incorporate a projection for outlier reconciliation dollars into the threshold methodology would be that FY 2023 outlier payments (which included the proposed estimated recoupment percentage for FY 2023 of 0.01 percent) would be 5.1 percent of total operating Federal payments plus total outlier payments. Therefore, the proposed

operating outlier offset to the standardized amount is 0.949 (1 − 0.051).

We invited public comment on our proposed methodology for projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed-loss cost outlier threshold for FY 2023.

We did not receive any comments on the proposed methodology, and for the reasons discussed in the proposed rule and in this final rule, we are finalizing the methodology described previously for incorporating the outlier reconciliation in the outlier threshold calculation. Therefore, for this final rule we used the same steps described previously and in the proposed rule to incorporate a projection of operating outlier payment reconciliations for the calculation of the FY 2023 outlier threshold calculation. The March 2022 HCRIS contained data for 15 hospitals. As stated previously, while we proposed to use the March 2022 HCRIS extract to calculate the reconciliation adjustment for this FY 2023 IPPS final rule, we also stated that similar to the FY 2022 final rule, we may also consider the use of more recent data that may become available for purposes of projecting the estimate of operating outlier reconciliation used in the calculation of the final FY 2023 outlier threshold. Data for 2 additional outlier reconciliations were made available to CMS outside of the March 2022 HCRIS update. Similar to our discussion of the estimated operating outlier reconciliation for FY 2021 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59036) and FY 2022 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45535), we believe supplementing with 2 hospitals' outlier reconciliation data will lend additional accuracy to project the estimate of operating outlier reconciliation used in the calculation of the outlier threshold. Therefore, in order to use the most complete data for FY 2017 cost reports, we are using the March 2022 HCRIS extract, supplemented by these 2 additional hospitals' data for this FY 2023 IPPS final rule. Based on March 2022 HCRIS and supplemental data for 2 hospitals, a total of 17 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $17,153,313 (Step 2). The total Federal operating payments based on the March 2022 HCRIS and supplemental data for 2 hospitals is $ 88,414,357,653 (Step 3). The ratio (Step 4) is a negative 0.019401 percent, which, when rounded to the second digit, is negative 0.02 percent. Therefore, for FY 2023, using the finalized methodology, we incorporated a projection of operating IPPS outlier reconciliation dollars by targeting an outlier threshold at 5.12 percent [5.1 percent − (− 0.02 percent)]. As noted previously, when the percentage of operating outlier reconciliation dollars to total Federal operating payments is negative (such is the case when the aggregate amount of outlier reconciliation is negative), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars.

(b) Reduction to the FY 2023 Capital Standard Federal Rate by an Adjustment Factor To Account for the Projected Proportion of Capital IPPS Payments Paid as Outliers

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we proposed to reduce the FY 2023 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement would be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments.

For FY 2023, we proposed to use the same methodology from FY 2020 to adjust the FY 2023 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. Similar to FY 2020, as part of our proposal for FY 2023 to incorporate into the outlier model the total outlier reconciliation dollars from the most recent and most complete fiscal year cost report data, we also proposed to adjust our estimate of FY 2023 capital outlier payments to incorporate a projection of capital outlier reconciliation payments when determining the adjustment factor to be applied to the capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers (that is, the capital outlier payment adjustment factor). To do so, we proposed to use the following methodology, which generally parallels the proposed methodology to incorporate a projection of operating outlier reconciliation payments for the FY 2023 outlier threshold calculation.

Step 1.—Use the Federal FY 2017 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude SCHs that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule. We used the December 2021 HCRIS extract for the proposed rule and we stated that we expect to use the March 2022 HCRIS extract for the FY 2023 final rule. Similar to the FY 2022 final rule, we stated that we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2023 adjustment to the FY 2023 capital standard Federal rate.

Step 2.—Calculate the aggregate amount of the historical total of capital outlier reconciliation dollars (Worksheet E, Part A, Line 93, Column 1) using the Federal FY 2017 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total capital Federal payments using the Federal FY 2017 cost reports from Step 1. The total capital Federal payments consist of the capital DRG payments, including capital indirect medical education (IME) and capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation payments (Worksheet E, Part A, Line 93, Column 1). We note that a negative amount on Worksheet E, Part A, Line 93 for capital outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments for FY 2017. This percentage amount would be used to adjust the estimate of capital outlier payments for FY 2023 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, we proposed that the estimate of capital outlier payments for FY 2023 would be determined by adding the percentage in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.) Because the aggregate capital outlier reconciliation dollars from Step 2 are negative, the estimate of capital outlier payments for FY 2023 under

our proposed methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold.

Similarly, for the FY 2023 proposed rule, we used the December 2021 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For this FY 2023 final rule, we proposed to use the latest quarterly HCRIS extract that is publicly available at the time of the development of that rule which, for FY 2023, would be the March 2022 extract. As previously noted, we stated that may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2023 adjustment to the FY 2023 capital standard Federal rate.

For the FY 2023 proposed rule, the estimated percentage of FY 2023 capital outlier payments otherwise determined using the shared outlier threshold was 5.56 percent (estimated capital outlier payments of $394,593,407 divided by (estimated capital outlier payments of $394,593,407 plus the estimated total capital Federal payment of $6,707,033,365)). Based on the December 2021 HCRIS, 9 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $759,945 (Step 2). The total Federal capital payments based on the December 2021 HCRIS was $7,992,953,494 (Step 3) which results in a ratio (Step 4) of -0.01 percent. Therefore, for FY 2023, taking into account projected capital outlier reconciliation payments under our proposed methodology would decrease the estimated percentage of FY 2023 aggregate capital outlier payments by 0.01 percent.

As discussed in section III.A.2. of this Addendum, we proposed to incorporate the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2023.

We invited public comment on our proposed methodology for projecting an estimate of capital outlier reconciliation and incorporating that estimate into the modeling of the estimate of FY 2023 capital outlier payments for purposes of determining the capital outlier adjustment factor.

We did not receive comments about the proposed capital outlier reconciliation methodology. Therefore, we are finalizing the methodology for projecting an estimate of capital outlier reconciliation as previously described. We stated in the proposed rule that while we expect to use the March 2022 HCRIS extract for the FY 2023 final rule, similar to the FY 2022 final rule, we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2023 adjustment to the FY 2023 capital standard Federal rate. For this final rule, for projecting the estimate of capital outlier reconciliation, similar to our projection of the estimate of operating outlier reconciliation, we are using cost report data of 12 hospitals from the March 2022 HCRIS supplemented for 2 hospitals for a total of 14 hospitals, which we believe will lend additional accuracy to the projection of estimated capital outlier reconciliation for FY 2023. We note that a difference in the number of cost reports for the operating and capital outlier reconciliation projections is possible and may be due to new hospitals defined in the regulations at 42 CFR 412.300(b) that may receive capital cost-based payments (in lieu of Federal rate payments), and therefore would not receive capital outlier payments. As a result, capital outlier reconciliation is not applicable to such hospitals since there is no capital outlier payment.

Based on the March 2022 HCRIS and supplemental data for 2 hospitals, 14 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $1,101,225 (Step 2). The total Federal capital payments based on the March 2022 HCRIS is approximately $7,995,731,783 (Step 3). The ratio (Step 4) is a negative 0.013773 percent, which, when rounded to the second digit, is negative 0.01 percent (Step 4). Therefore, for FY 2023, taking into account projected capital outlier reconciliation payments under our methodology will decrease the estimated percentage of FY 2023 aggregate capital outlier payments by 0.01 percent. Accordingly, under our methodology as previously discussed, we are applying the 0.01 percent adjustment to our estimate of the capital outlier percentage (described below).

To determine the FY 2023 IPPS fixed-loss amount (shared threshold) in this final rule (as discussed in greater detail later in this section), after consideration of public comments we are incorporating modifications to our proposed methodology. Specifically, one of the modifications we are making is to determine the shared threshold as an average of the thresholds calculated when including and excluding COVID–19 cases. Because of this averaging, it is necessary to make a minor modification to the proposed methodology for incorporating the estimate of capital outlier reconciliation into the modeling of the estimate of FY 2023 capital outlier payments for purposes of determining the capital outlier adjustment factor. (We refer the reader to the discussion below in section II.A.4.j.(2). of this Addendum for complete details regarding the calculation of the shared threshold for FY 2023 based on the averaging of the thresholds as calculated including and excluding COVID–19 cases.)

Therefore, to incorporate the estimate of capital outlier reconciliation, after calculating the shared threshold based on the average of the thresholds as calculated with and without COVID–19 cases, for this final rule we are using the same steps as described in the proposed rule to reduce the FY 2023 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. However, with regard to Step 5 above, as discussed in more detail below, for this final rule we are determining the estimate of capital outlier payments for FY 2023 by adding the percentage in Step 4 to the estimated percentage of capital outlier payments calculated by averaging the estimated percentage of capital outlier payments including and excluding COVID–19 cases.

As explained previously, once a shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Therefore, our modified methodology produces two separate estimates of the percentage of capital outlier payments to total capital payments. One estimate is based on the shared threshold that was determined using all cases in the FY 2021 claims data, including COVID–19 cases. The other estimate is based on the shared threshold that was determined using FY 2021 claims data excluding COVID–19 cases. We then averaged these two estimates of capital outlier payments to total capital payments to estimate the percentage of capital outlier payments in FY 2023 using the final FY 2023 shared outlier threshold. This approach is also consistent with our belief that it is reasonable to assume there will be fewer COVID–19 cases in FY 2023 as compared to FY 2021 (as discussed later in this section and in section I.F of the preamble to this final rule).

For this final rule, we first determined a capital outlier percentage of 5.66 percent (estimated capital outlier payments of $406,733,862 divided by $7,190,928,057 (estimated capital outlier payments of $406,733,862 plus the estimated total capital Federal payment of $6,784,194,195)) based on the shared threshold that was calculated using all claims, including COVID–19 cases. We next determined a capital outlier percentage of 5.40 percent (estimated capital outlier payments of $346,066,050 divided by $6,412,816,596 (estimated capital outlier payments of $346,066,050 plus the estimated total capital Federal payment of $6,066,750,547)) based on the shared threshold that was calculated excluding COVID–19 cases. Therefore, taking the average of these two estimates, we estimate capital outlier payments to be 5.53 percent of total capital payments prior to incorporating the estimate of capital outlier reconciliation. Finally, under our methodology for accounting for capital outlier reconciliation as discussed previously, we are applying the 0.01 percent adjustment to this estimate of the capital outlier percentage as calculated using the average of the two estimates based on the shared thresholds including and excluding COVID–19 data of 5.53 percent, as previously described. Therefore, accounting for estimated capital outlier reconciliation, we estimate outlier payments for capital-related PPS payments will equal 5.52 percent (5.53 percent—0.01 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2023.

(2) FY 2023 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the FY 2023 outlier threshold, we simulated payments by applying FY 2023 payment rates and policies using cases from the FY 2021 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the proposed FY 2023 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2021 to FY 2023. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we proposed to use the following methodology to calculate the charge inflation factor for FY 2023:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals who have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate of-change in charges per case. We note this is consistent with the methodology used since FY 2014.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS. As noted previously, we are removing allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835–58842).
- Because this payment simulation uses the FY 2023 relative weights, consistent with our policy discussed in section IV.I. of the preamble to this final rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. As discussed in section II.E.2.b. of the preamble of this final rule, we are applying an adjustment to account for certain cases that group to MS–DRG 018 in calculating the FY 2023 relative weights and for purposes of budget neutrality and outlier simulations.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years since we typically use claims data for the fiscal year that is 2 years prior to the upcoming fiscal year.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change.

For FY 2023, under our policy of computing the charge inflation factor using the publicly available Federal fiscal year period, we would ordinarily use charge data from the MedPAR files for Federal fiscal years 2020 and 2021 to compute the 1-year average annual rate-of-change in charges per case. Specifically, for the proposed rule, we would ordinarily use the December 2020 MedPAR file of FY 2020 (October 1, 2019, through September 30, 2020) charge data and the December 2021 MedPAR file of FY 2021 (October 1, 2021, through September 30, 2021) charge data to compute the proposed charge inflation factor. However, based on our analysis, the charge inflation factors calculated using these two most recently available years of MedPAR claims data (FY 2020 and FY 2021) are abnormally high as compared to recent historical levels prior to the COVID–19 PHE period. Specifically, in the proposed rule we stated that we calculated a 1-year average annual rate-of-change in charges per case of approximately 10 percent based on the FY 2020 and FY 2021 MedPAR claims data, as compared to approximately 6 percent based on the FY 2018 and 2019 MedPAR claims data for the two most recent Federal fiscal year time periods prior to the PHE. We stated that we believe this abnormally high charge inflation as compared to historical levels was partially due to the high number of COVID–19 cases with higher charges that were treated in IPPS hospitals in FY 2021. As discussed in section I.F of the preamble of this final rule, we believe there will be fewer COVID–19 cases in FY 2023 than in FY 2021. Therefore, we do not believe it is reasonable to assume charges will continue to increase at these abnormally high rates.

Therefore, in the FY 2023 IPPS/LTCH proposed rule (87 FR 28667), we proposed for FY 2023 to use the same methodology as FY 2020, with a proposed modification to use the most recent 1-year average annual rate-of-change in charges per case for the period prior to the COVID–19 PHE, and based on the same data used in the FY 2021 IPPS/LTCH PPS final rule to determine the charge inflation factor for the proposed rule. We further noted that this is the same data used to determine the charge inflation factor for the FY 2022 IPPS/LTCH PPS rulemaking. Specifically, for FY 2023, we proposed to use the MedPAR files for the two most recent available Federal fiscal year time periods prior to the COVID–19 PHE to calculate the charge inflation factor. Specifically, for the proposed rule we proposed to use the March 2019 MedPAR file of FY 2018 (October 1, 2017, to September 30, 2018) charge data (released for the FY 2020 IPPS/LTCH PPS final rule) and the March 2020 MedPAR file of FY 2019 (October 1, 2018, to September 30, 2019) charge data (released for the FY 2021 IPPS/LTCH PPS final rule) to compute the proposed charge inflation factor. We proposed that for the FY 2023 IPPS/LTCH PPS final rule, we would continue to use the charge inflation estimate from the FY 2021 IPPS/LTCH PPS final rule. Under this proposed methodology, to compute the 1-year average annual rate-of-change in charges per case for FY 2023, we compared the average covered charge per case of $61,578.82 ($584,618,863,834/9,493,830 cases) from October 1, 2017, through September 31, 2018, to the average covered charge per case of $65,522.10 ($604,209,834,327/9,221,466 cases) from October 1, 2018, through September 31, 2019. This rate-of-change was 6.4 percent (1.06404) or 13.2 percent over 2 years (1.13218). Because we proposed to use the FY 2021 MedPAR for the FY 2023 ratesetting, we applied a factor of 13.2 percent over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified previously.

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28667–28668), we also solicited comments on the alternative approach of

using the data we would ordinarily use to determine the charge inflation factor for purposes of this FY 2023 rule (that is, charge data from FYs 2020 and 2021 to compute the 1-year average annual rate of change in charges per case), and noted that under this alternative approach, if finalized, we would anticipate using more recently updated data from FYs 2020 and 2021 for purposes of the FY 2023 IPPS/LTCH PPS final rule. As previously noted, in order to facilitate comments on our alternative approach of using the FY 2021 MedPAR claims for purposes of FY 2023 ratesetting but without the proposed modifications to our usual methodologies, including use of the same data that we would ordinarily use for purposes of determining the charge inflation factor for this FY 2023 rulemaking, and which we stated we may consider finalizing for FY 2023 based on consideration of comments received, we made available budget neutrality and other ratesetting adjustments, including the charge inflation factor, calculated under this alternative approach, which can be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We included in a supplemental data file the following: budget neutrality factors, charge inflation factor, the CCR adjustment factors, an impact file and outlier threshold based on this alternative approach. Consistent with historical practice, we stated that if we were to finalize this alternative approach, we would use the most recent available data for the final rule, as appropriate.

As discussed previously, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28668), we proposed to establish the FY 2023 outlier threshold using hospital CCRs from the December 2021 update to the Provider-Specific File (PSF), the most recent available data at the time of developing the proposed rule. We proposed to apply the following edits to providers' CCRs in the PSF. We stated that we believe these edits are appropriate in order to accurately model the outlier threshold. We first searched for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replaced these CCRs with the statewide average CCR for the upcoming fiscal year. We also assigned the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We did not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2023, we also proposed to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained further in this section).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28668) we stated that ordinarily, for the proposed rule, we would apply a proposed adjustment factor to adjust the CCRs from the December 2021 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2020 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2021 update of the PSF. However, the operating and capital CCR adjustment factors based on the data we ordinarily would use are above 1.0. Since the implementation of our new methodology to adjust the CCRs in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), the operating and capital CCR adjustment factors have typically been below 1.0 (for example, operating and capital CCR adjustment factors of approximately 1.03 and 1.03, respectively, based on the December 2020 and December 2021 updates to the PSF as compared to operating and capital CCR adjustment factors of approximately 0.97 and 0.96, respectively, based on the March 2019 and March 2020 updates to the PSF). As stated in section I.F. of the preamble to this final rule, we believe this abnormally high CCR adjustment factor as compared to historical levels is partially due to the high number of COVID–19 cases with higher charges that were treated in IPPS hospitals in FY 2021. As we previously stated, we believe there will be fewer COVID–19 cases in FY 2023 than in FY 2021. Therefore, we stated that we do not believe it is reasonable to assume CCRs will continue to increase at these abnormally high rates. Therefore, we proposed to adjust the CCRs from the December 2021 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2019 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2020 update of the PSF, which is the last update of the PSF prior to the PHE. We noted that this is the same data used to adjust the CCRs for the FY 2022 IPPS/LTCH PPS rulemaking. We stated that we believe using these data for the latest available period prior to the PHE, for which the percentage change in the national average case weighted operating CCR and capital CCR is below 1.0, is appropriate in light of our expectation that the CCRs will not continue to increase at these abnormally high rates for FY 2023. We noted that we used total transfer-adjusted cases from FY 2019 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison, because this would produce the true percentage change in the average case-weighted operating and capital CCR from 1 year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology, for the proposed rule, we calculated a March 2019 operating national average case-weighted CCR of 0.254027 and a March 2020 operating national average case-weighted CCR of 0.247548. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2019 operating national average case-weighted CCR from the March 2020 operating national average case-weighted CCR and then dividing the result by the March 2019 national operating average case-weighted CCR. This resulted in a proposed 1-year national operating CCR adjustment factor of 0.974495. In the proposed rule, we noted that because we proposed to use CCRs from the December 2021 update of the PSF for FY 2023, we applied a 1-year proposed national operating CCR adjustment.

We used this same proposed methodology to adjust the capital CCRs. Specifically, we calculated a March 2019 capital national average case-weighted CCR of 0.02073 and a March 2020 capital national average case-weighted CCR of 0.019935. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the March 2019 capital national average case-weighted CCR from the March 2020 capital national average case-weighted CCR and then dividing the result by the March 2019 capital national average case-weighted CCR. This resulted in a proposed 1-year national capital CCR adjustment factor of 0.96165. Because we proposed to use CCRs from the December 2021 update of the PSF for FY 2023, we applied a 1-year proposed national capital CCR adjustment.

As discussed in section I.F. of the proposed rule and in section I.O. of Appendix A of the proposed rule, we solicited comments on an alternative approach of using the data that we would ordinarily use for purposes of adjusting the CCRs for this FY 2023 rulemaking, which we stated we may consider finalizing for FY 2023 based on consideration of comments received. As previously noted, in order to facilitate comments on our alternative approach of using the FY 2021 MedPAR claims for purposes of FY 2023 ratesetting but without the proposed modifications to our usual methodologies, we made available supplemental data files, including the following: budget neutrality factors, charge inflation factor, the CCR adjustment factors, and outlier threshold based on this alternative approach. Consistent with historical practice, we stated in the proposed rule if we were to finalize this alternative approach, we would use the most recent available data for the final rule, as appropriate.

For purposes of estimating the proposed outlier threshold for FY 2023, we used a wage index that reflects the policies discussed in the proposed rule. This includes all of the following:

- The proposed frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act.
- The proposed out-migration adjustment as added by section 505 of Public Law 108–173.
- Incorporating the proposed FY 2023 low wage index hospital policy (described in section III. G. 4 of the FY 2023 IPPS/LTCH proposed rule (87 FR 28369)) for hospitals

with a wage index value below the 25th percentile, where the increase in the wage index value for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals.

• Incorporating our proposed policy (described in section III.N. of the preamble of the proposed rule) to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline.

If we did not take the aforementioned into account, our estimate of total FY 2023 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation).

As described in sections V.K. and V.L., respectively, of the preamble of this final rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We stated in the proposed rule that we do not believe that it is appropriate to include the proposed hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we proposed to exclude the estimated hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We noted in the proposed rule that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2023, we proposed to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We stated that we continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we stated that we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2023, we proposed to include estimated FY 2023 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

In addition, as discussed in section IV.E. of the preamble of the proposed rule, we proposed to establish a supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, beginning in FY 2023. We proposed to make interim payments of this proposed new supplement payment on a per-discharge basis. Consistent with the policy of including estimated uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold, as previously summarized, we proposed to use our authority under section 1886(d)(5)(I) of the Act to include the estimated supplemental payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we proposed to incorporate an estimate of FY 2023 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for the FY 2023 proposed rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) is a negative 0.013508 percent, which, when rounded to the second digit, is −0.01 percent. Therefore, for FY 2023, we proposed to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent − (−.01 percent)]. Under this proposed approach, we determined a proposed threshold of $43,214 and calculated total outlier payments of $4,709,906,314 and total operating Federal payments of $88,837,735,468. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.11 percent target, which reflected our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We noted that, if calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the proposed threshold would be $43,292. We proposed an outlier fixed-loss cost threshold for FY 2023 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, proposed estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus $43,214.

As previously noted, and as discussed further in section I.O of the Appendix A of this final rule, we also considered an alternative approach of using the FY 2021 MedPAR claims for purposes of FY 2023 ratesetting but without the proposed modifications to our usual methodologies, including use of the same data we would ordinarily use for purposes of this FY 2023 rulemaking to compute the charge inflation factors and CCR adjustment factors in determining the FY 2023 outlier fixed-loss amount for IPPS cases. Under this alternative approach, we estimated an outlier threshold of $58,798 rather than the proposed threshold of $43,214 noted previously.

Comment: Commenters expressed concern about the increase to the fixed-loss threshold for FY 2023. Several commenters acknowledged the steps CMS took to account for some of the COVID–19 pandemic-related factors that have driven the increase, which may not continue in FY 2023. Specifically, many commenters supported the use of pre-PHE data for charge inflation and CCR adjustment factors.

Several other commenters opposed the use of the charge inflation data and CCR adjustment factors from the period preceding the PHE for the following reasons.

• A commenter stated that the use of pre COVID–19 data for the charge inflation does not appear to consider the unusually high inflation currently facing hospitals. The commenter encouraged CMS to recognize that hospitals continue to experience atypical costs from COVID–19 care, along with historic inflation levels, continued labor shortages, and supply chain disruptions and to fully reflect these costs in the data and methodologies used for FY 2023.

• Another commenter believes that the charge inflation that has occurred during the PHE will continue as this trend has been consistent since before the pandemic.

• Another commenter stated that it does not support the use of an inflation factor preceding the COVID–19 PHE as this does not accurately reflect today's environment. The commenter stated that providers are experiencing the rise of inflation and additional costs that are not likely to resolve within the next fiscal year and while COVID–

19 hospitalizations may continue to decline, providers are also seeing higher acuity patients, many who delayed care and are now sicker and costlier to treat. The commenter recommended that CMS reevaluate the use of a pre-COVID–19 inflation factor and instead use 2021 data.

Some commenters supported the use of the FY 2021 claims data. Another commenter opposed the use of unadjusted FY 2021 claims data, stating that more recent data suggests that there should be far fewer high-cost COVID–19 cases in FY 2023 relative to FY 2021. This commenter suggested that CMS trim COVID–19 cases with costs that are more than three standard deviations from the geometric mean. Several other commenters suggested that CMS remove high-cost cases in MS–DRGs identified as COVID–19 related, while others suggested that CMS remove all COVID–19 cases. Other commenters suggested using a blend of FY 2019 and FY 2021 data, using a blend of FY 2019 and FY 2020 data with COVID–19 cases removed, reducing the weight of COVID–19 cases in the FY 2021 data by 50 percent, using claims data from prior to the PHE, or using an average of the current FY 2022 threshold with the newly proposed threshold. MedPAC suggested calculating the FY 2023 fixed-loss amount as an average of the outlier fixed-loss amounts calculated with and without COVID–19 cases in the FY 2021 data. MedPAC believes that this approach would be consistent with the approach CMS proposed for calculating the MS–DRG relative weights and would reflect the assumption that there will be fewer COVID–19 cases in FY 2023 as compared to FY 2021.

A commenter suggested that CMS model the inclusion of NCTAP payments and the increased payments for COVID–19 cases provided by the CARES Act in the FY 2021 claims data when calculating the fixed-loss threshold. This commenter stated that conservatively, the PHE is anticipated to end no earlier than mid-October 2022, which means that NCTAP payments will continue for all of FY 2023. This commenter stated that in using the FY 2021 MedPAR data, CMS is assuming that COVID–19 hospitalizations in FY 2023 will mirror those in FY 2021, which implies that the PHE will be further renewed, and that the increased payments for COVID–19 cases provided by the CARES Act will continue in FY 2023. (Section 3710 of the CARES Act provides for an increase in the MS–DRG weighting factor of 20 percent for an individual diagnosed with COVID–19 discharged during the period of the PHE for COVID–19.)

Some commenters suggested that CMS phase in the large proposed increase to the fixed-loss threshold over time. Many commenters suggested that CMS reexamine its methodology more closely and adopt additional changes to offset substantial increases in the outlier threshold. A commenter suggested that CMS better account for the data anomalies created by the pandemic until patient mix becomes more predictable and the data used for ratesetting reflects a more stable healthcare environment.

A commenter stated they believe that inadequate market basket updates in prior years and for the upcoming fiscal year do not accurately capture increases in costs which also drive increases to the outlier threshold. The commenter stated that smaller market basket adjustments leave IPPS payments too low, pushing the costs of too many claims above the MS–DRG payment amount and driving untenable growth in the fixed loss threshold. The commenter requested that CMS calculate the final rule outlier threshold using a higher market basket percentage increase.

Response: We appreciate commenters' support regarding the use of pre-PHE data for charge inflation and CCR adjustment factors. With respect to those commenters that opposed the use of this data, it appears that these commenters believe that the charge inflation factor is a measure of cost inflation, and that a higher charge inflation factor would more accurately account for the costs of providing medical care. The charge inflation factor is typically a 1-year average annual rate-of-change in charges which is applied to inflate the charges on the MedPAR claims by 2 years since we typically use claims data for the fiscal year that is 2 years prior to the upcoming fiscal year. For the reasons discussed in the proposed rule, we continue to believe that use of the pre-PHE data for the FY 2023 charge inflation and CCR adjustment factors is most appropriate given our belief that there will be fewer COVID–19 cases in FY 2023 than in FY 2021, based on the information available at this time. As mentioned in the proposed rule, the charge inflation factors calculated using the two most recently available years of MedPAR claims data (FY 2020 and FY 2021) are abnormally high as compared to recent historical levels prior to the COVID–19 PHE period. With regard to the CCR adjustment factors, the operating and capital CCR adjustment factors based on the data we ordinarily would use are above 1.0 while the operating and capital CCR adjustment factors have typically been below 1.0. We also continue to believe that these abnormal charges were partially due to the high number of COVID–19 cases with higher charges. Because we anticipate that there will be fewer COVID–19 cases in FY 2023 as compared to FY 2021, based on the information available at this time and as explained previously, we believe the use of the most recent available data prior to the COVID–19 PHE is appropriate for FY 2023. We also note that lower charges per case due to a lower charge inflation factor and lower CCRs based on a CCR adjustment factor below 1 will result in lower costs per case and will result in a lower threshold in order to ensure outlier payments are 5.1 percent of total payments. As discussed in the proposed rule, under the alternative approach of using the same data we would ordinarily use for purposes of this FY 2023 rulemaking to compute the charge inflation factors and CCR adjustment factors in determining the FY 2023 outlier fixed-loss amount for IPPS cases, we estimated an outlier threshold of $58,798 rather than the proposed threshold of $43,214.

With respect to commenters' recommendations of various approaches to modify the data or methodology to calculate the fixed-loss threshold, we continue to recognize that there is uncertainty regarding the utilization and costs that hospitals will experience in FY 2023. However, based on the information available at this time on the trajectory of the COVID–19 PHE, consistent with the discussion in section I.F. of the preamble to this final rule, we believe averaging the outlier-fixed loss thresholds calculated using FY 2021 data including and excluding COVID–19 claims, as suggested by MedPAC, would best reflect our belief that it is reasonable to assume there will be fewer COVID–19 hospitalizations among Medicare beneficiaries in FY 2023 than there were in FY 2021 (as discussed in section I.F of the preamble to this final rule). While another commenter recommended to reduce the weight of COVID–19 cases in the FY 2021 data by 50 percent, we believe that averaging the outlier-fixed loss thresholds as calculated with and without COVID–19 claims in the FY 2021 data as described would be most consistent with the approach we proposed and are finalizing for calculating the MS–DRG relative weights for FY 2023, as discussed in section II.E.2.c of the preamble to this final rule. As discussed below, we are adopting the approach suggested by MedPAC when determining the FY 2023 outlier fixed loss amount.

With regard to averaging the data with claims pre COVID–19 for modeling the fixed loss threshold, we note that the FY 2021 and FY 2022 thresholds used claims from FY 2019 to set the fixed loss threshold. The thresholds in FY 2021 and FY 2022 were $29,064 and $30,988 respectively. As noted in the proposed rule, if we made no modifications to our methodology to set the FY 2023 fixed loss threshold, the proposed fixed loss threshold would have been $58,798. Even with our modifications to the methodology that we proposed in the FY 2023 IPPS/LTCH proposed rule, the proposed threshold was lowered from $58,798 to $43,214. Because of this large variance in the thresholds as determined using pre and post COVID–19 data, we do not believe it would be appropriate to average the data used to calculate the threshold with pre COVID–19 data (including, as suggested by the commenters, by using a blend of FY 2019 and FY 2021 data, or using a blend of FY 2019 and FY 2020 data with COVID–19 cases removed) as we do not believe this approach would provide a reasonable estimate of outlier payments for FY 2023 as 5.1 percent of estimated total payments for FY 2023.

We also agree with the commenter that suggested that we include the increase in payments for COVID–19 cases provided by the CARES Act, based on the information available at this time on the trajectory of the COVID–19 PHE. Therefore, we incorporating these two suggested modifications to our proposed methodology for determining the FY 2023 outlier fixed-loss amount. Specifically, we calculated two fixed-loss thresholds, one using FY 2021 claims data including COVID–19 cases that reflect the payment increase provided by the CARES Act and one using FY 2021 claims data excluding COVID–19 cases, and then averaged these two fixed-loss thresholds to determine the final fixed-loss threshold for

FY 2023. We believe these adjustments to our proposed methodology will best reflect a reasonable estimation of the case mix and relative resource use of FY 2023 cases based on the information available at this time.

With respect to the comment that we should include NCTAP payments in the COVID–19 cases in the FY 2021 claims data, we note that, as stated in the Interim Final Rule Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency (85 FR 71142), the NCTAP will not be included as part of the calculation of the operating outlier payments. Therefore, including the NCTAP payments in the COVID–19 cases would not impact the calculation of the outlier threshold.

With respect to the comment that CMS phase in the large proposed increase to the fixed-loss threshold over time, if we used a phase in approach then the fixed loss threshold for FY 2023 would not meet the requirement that outlier payments result in 5.1 percent of estimated total payments.

In response to the commenters that suggested that CMS reexamine its methodology more closely and adopt additional changes to offset substantial increases in the outlier threshold, in addition to the proposed modifications in the proposed rule, we are making additional changes to the methodology for FY 2023 in this final rule in response to comments, specifically the averaging of the two fixed-loss thresholds and accounting for the payment increase provided by the CARES Act.

With respect to the commenter that suggested that CMS better account for the data anomalies created by the pandemic until patient mix becomes more predictable and the data used for ratesetting reflects a more stable healthcare environment, as previously discussed, we recognize that there is uncertainty regarding the utilization and costs that hospitals will experience in FY 2023. Therefore, we believe that based on the information available at this time on the trajectory of the COVID–19 PHE, our averaging of the outlier-fixed loss thresholds as previously described represents the best estimate of the fixed loss threshold for FY 2023.

With respect to commenters who expressed concerns regarding the effect of the market basket update on the calculation of the fixed-loss threshold, we refer readers to section V.A of the preamble of this final rule for our response to comments about the market basket update. We note, for this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy (which incorporates more recent historical CPI growth, estimated impacts of the Russia/Ukraine war, expectations regarding changes to Federal Reserve interest rates, and the estimated impacts of continued tight labor markets).

Comment: A commenter requested that CMS consider whether it is appropriate to include extreme cases when calculating the threshold. This commenter explained that high charge cases have a significant impact on the threshold. The commenter stated that it examined the data to understand the factors that drove an increase of over $7,000 in the threshold between FY 2017 and FY 2022 and stated that it observed that the inclusion of extreme cases in the calculation of the threshold, the rate of which are increasing over time, significantly impacts CMS' determination of the fixed-loss threshold. If this trend continues (that is, if the number (and proportion) of extreme cases continues to increase each year), the commenter stated that the impact of this population of cases on the threshold will likewise increase. Thus, the commenter recommended that CMS carefully consider what is causing this trend, whether the inclusion of these cases in the calculation of the threshold is appropriate, or whether a separate outlier mechanism should apply to these cases that more closely hews outlier payments to marginal costs. The commenter believes this is consistent with the calculation process used for IPPS rate setting generally and that a 2013 OIG Report, Medicare Hospital Outlier Payments Warrant Increased Scrutiny, *https://oig.hhs.gov/oei/reports/oei-06-10-00520.asp*, concurs with this view. Another commenter suggested that CMS take steps to ensure that the outlier threshold approximates the FY 2022 outlier threshold.

Response: As we explained when responding to a similar comment in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38526), the methodology used to calculate the outlier threshold includes all claims in order to account for all different types of cases, including high charge cases, to ensure that CMS meets the 5.1 percent target. As the commenter pointed out, the volume of these cases continues to rise, making their impact on the threshold significant. We believe excluding these cases would artificially lower the threshold. We believe it is important to include all cases in the calculation of the threshold no matter how high or low the charges. Including these cases with high charges lends more accuracy to the threshold, as these cases have an impact on the threshold and continue to rise in volume. Therefore, we believe the inclusion of the high-cost outlier cases in the calculation of the outlier threshold is appropriate.

Also, with regard to the 2013 OIG report that the commenter references, this report studied the distribution of outlier payments and made recommendations based on the OIG findings, but did not mention concerns or make any recommendations with regard to the calculation of the outlier threshold. Therefore, we do not agree with the commenter that the OIG report concurs with its view.

Comment: A commenter stated that it believes that ordinarily it is important to the process for setting the outlier threshold that CMS accurately calculate prior year actual payment comparisons to the 5.1 percent target. Without doing so, the commenter stated it is impossible for CMS to appropriately modify its methodology to achieve an accurate result. The commenter also noted that CMS' estimates of past outlier payments also routinely exceed the calculations of outlier payments based on HCRIS cost report data. The commenter emphasized the importance of CMS using the most recent data available to more accurately assess the outlier payment level. The commenter stated that CMS has generally fallen short of its 5.1 percent outlier target virtually every FY since at least 2013 (the exceptions being meeting it in FY 2019 and exceeding it during the PHE) and yet is still proposing a significant increase in the threshold this year with no rationale offered to explain the prior years' shortfalls in outlier payments. Another commenter stated that to the extent an increase in the fixed loss threshold is necessary, it should be limited to the market basket increase.

Response: As noted previously, section 1886(d)(5)(A)(iv) of the Act states that outlier payments may not be not less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year. With regard to the comment that CMS has generally fallen short of its 5.1% outlier target virtually every FY since at least 2013 (the exceptions being meeting it in FY 2019 and exceeding it during the PHE) and yet is still proposing a significant increase in the threshold this year with no rationale offered to explain the prior year shortfalls in payment, as we have previously stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49783), when we conduct our modeling to determine the outlier threshold, we generally factor in all payments and policies that would affect actual payments for the current year in order to estimate that outlier payments are 5.1 percent of total MS–DRG payments. While we recognize that outlier payments sometimes are below the 5.1 percent target in prior fiscal years, we do not believe that these lower payouts are relevant to the current fiscal year because they do not lend greater accuracy to the estimate of payments that are 5.1 percent of total MS–DRG payments for the upcoming fiscal year for FY 2023. We also note that in response to concerns such as the commenters', over the years we have modified our outlier threshold calculation by changing the way we adjust the CCRs, changing the measure of inflation and incorporating an adjustment for outlier reconciliation. While the commenter has expressed their concern, we note they have not provided any suggestions for how CMS can improve the calculation of the outlier threshold (based on the concerns expressed by this commenter). As in prior years, CMS will continue to evaluate our methodology of calculating the fixed loss threshold and consider any suggestions made by the commenters to improve the accuracy of the calculation of the outlier threshold.

We did not receive comments on our proposal to use the estimated per-discharge supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals to hospitals eligible for the supplemental payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology. Therefore, we are finalizing as proposed without modification to include the estimated per-discharge supplemental payments to hospitals eligible for the

supplemental payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

After consideration of the public comments we received, we are finalizing the methodology we proposed to calculate the final outlier threshold with the two modifications described previously. That is, we are using the same methodology as proposed, which includes the use of charge inflation data and the CCR adjustment factors from the period preceding the PHE, with the modification that we calculated two fixed-loss thresholds using this methodology, one using FY 2021 claims data including COVID–19 cases that reflect the payment increase provided by the CARES Act and one using FY 2021 claims data excluding COVID–19 cases, and then averaged these two fixed-loss thresholds to determine the final fixed-loss threshold for FY 2023.

As discussed previously, we are finalizing as proposed to calculate charge inflation using the publicly available FY 2018 and FY 2019 claims data and to incorporate a projection of outlier payment reconciliations for the FY 2023 outlier threshold calculation. For the FY 2023 final outlier threshold, we used the March 2019 MedPAR file of FY 2018 (October 1, 2017 through September 30, 2018) charge data (released in conjunction with the FY 2020 IPPS/LTCH PPS final rule) and the March 2020 MedPAR file of FY 2019 (October 1, 2018 through September 30, 2019) charge data (released in conjunction with the FY 2021 IPPS/LTCH PPS final rule) to determine the charge inflation factor. To compute the 1 year average annual rate of change in charges per case, we compared the average covered charge per case of $61,578.82 ($584,618,863,834/9,493,830 cases) from October 1, 2017 through September 31, 2018, to the average covered charge per case of $65,522.10 ($604,209,834,327/9,221,466 cases) from October 1, 2018 through September 31, 2019. This rate-of-change was 6.4 percent (1.06404) or 13.2 percent over 2 years (1.13218) . Because are using the FY 2021 MedPAR for the FY 2023 ratesetting, we applied a factor of 13.2 percent over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified previously.

For FY 2023, as we have done in the past, we are establishing the FY 2023 outlier threshold using hospital CCRs from the March 2022 update to the Provider-Specific File (PSF); the most recent available data at the time of the development of the final rule. We applied the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replaced these CCRs with the statewide average CCR for the upcoming fiscal year. We also assigned the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We did not apply the adjustment factors described below to hospitals assigned the statewide average CCR. For FY 2023, we also are continuing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below).

As previously discussed, ordinarily, for the final rule, using the latest available data at the time of this final rule, we would apply an adjustment factor to adjust the CCRs from the March 2022 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2021 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2022 update of the PSF. However, for the reasons as previously discussed, we are finalizing as proposed to adjust the CCRs from the March 2022 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2019 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2020 update of the PSF, which is the last update of the PSF prior to the PHE. We note that this is the same data used to adjust the CCRs for the FY 2022 IPPS/LTCH PPS rulemaking. As previously stated, we believe using these data for the latest available period prior to the PHE, for which the percentage change in the national average case weighted operating CCR and capital CCR is below 1.0, is appropriate in light of our expectation that the CCRs will not continue to increase at these abnormally high rates for FY 2023. We note that we used total transfer-adjusted cases from FY 2019 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison, because this would produce the true percentage change in the average case-weighted operating and capital CCR from 1 year to the next without any effect from a change in case count on different sides of the comparison.

Using this methodology, for this final rule, we calculated a March 2019 operating national average case-weighted CCR of 0.254027 and a March 2020 operating national average case-weighted CCR of 0.247548. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2019 operating national average case-weighted CCR from the March 2020 operating national average case-weighted CCR and then dividing the result by the March 2019 national operating average case-weighted CCR. This resulted in a 1-year national operating CCR adjustment factor of 0.974495. Similar to the proposed rule, because we are using CCRs from the March 2022 update of the PSF for FY 2023, we applied a 1-year national operating CCR adjustment.

We used this same methodology to adjust the capital CCRs. Specifically, we calculated a March 2019 capital national average case-weighted CCR of 0.02073 and a March 2020 capital national average case-weighted CCR of 0.019935. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the March 2019 capital national average case-weighted CCR from the March 2020 capital national average case-weighted CCR and then dividing the result by the March 2019 capital national average case-weighted CCR. This resulted in a 1-year national capital CCR adjustment factor of 0.96165. Similar to the proposed rule, because we use CCRs from the March 2022 update of the PSF for FY 2023, we applied a 1-year national capital CCR adjustment.

As discussed previously, consistent with the proposed rule, for FY 2023, we applied the following policies (as discussed in more detail earlier):

- We used a wage index based on the FY 2023 wage index that hospitals will be paid. This included our final policy to include the wage data of hospitals that have reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) in the calculation of the rural floor (see section III.G.1. of the preamble of this final rule for a complete discussion on this policy); application of the imputed floor adjustment, the frontier State floor adjustment in accordance with section 10324(a) of the Affordable Care Act, and the out migration adjustment as added by section 505 of Public Law 108–173; and application of our wage index policies to: (1) increase the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals, and (2) apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline (described in section III. N of the preamble of this final rule). As stated previously, if we did not take the above into account, our estimate of total FY 2023 payments would be too low, and, as a result, our outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.12 percent of total payments (which reflects the estimate of outlier reconciliation calculated for this final rule).
- We excluded the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.
- We used the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.
- Based on the policy finalized, as previously described, we used the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1 of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are finalizing to incorporate an estimate of FY 2023 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for this FY

2023 final rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) is a negative 0.019401 percent, which when rounded to the second digit, is 0.02 percent. Therefore, for FY 2023, we incorporated a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.12 percent [5.1 percent − (0.02 percent)].

As previously discussed, after consideration of the comments we received, we are modifying elements of our calculation of the fixed-loss threshold by averaging the fixed-loss thresholds calculated including and excluding COVID–19 cases in the FY 2021 claims data. We also agreed with the commenter's suggestion that we include the payment increase for COVID–19 cases provided by the CARES Act. As discussed previously, we calculated two fixed-loss thresholds, one using FY 2021 claims data including COVID–19 cases that reflect the payment increase provided by the CARES Act and one using FY 2021 claims data excluding COVID–19 cases, and then averaged these two fixed-loss thresholds to determine the final fixed-loss threshold for FY 2023.

Based on this finalized averaging approach, the following are the steps we used to determine the final fixed-loss threshold for FY 2023 using FY 2021 claims data.

Step 1: Using all claims, which included COVID–19 cases and incorporating the payment increase provided by the CARES Act, we determined a threshold of $39,389 and calculated total outlier payments of $4,658,400,549 and total operating Federal payments of $86,325,462,972. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.12 percent target, which reflects our methodology to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum).

Step 2: Excluding COVID–19 cases, we determined a threshold of $38,328 and calculated total outlier payments of $4,073,729,554 and total operating Federal payments of $75,488,568,943. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.12 percent target, which reflects our methodology to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum).

Step 3: We averaged the two fixed-loss thresholds from steps 1 and 2 to determine a final fixed-loss threshold for FY 2023 of $38,859 (($39,389 + $38,328)/2)).

We are finalizing an outlier fixed-loss cost threshold for FY 2023 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals and any addon payments for new technology, plus $38,859.

Comment: A commenter stated that the COVID–19 PHE increased case acuity and payments due to the suspension of the 2% sequestration. Therefore, the commenter recommended that payments should be adjusted from the FY 2022 estimated outlier threshold because of the temporal nature of these additional payments.

Response: We appreciate the commenter's input. The sequestration reduction is a 2-percent reduction to overall payments and is applied after calculating individual payments such as outlier payments. Therefore, CMS has not made any adjustments that consider the 2-percent reduction in our modeling of outlier payments. As a result, no change to the outlier model for FY 2023 is necessary. With regard to the commenter noting the increased case acuity, we refer the reader to section I.F. of this FY 2023 IPPS/LTCH final rule for a discussion of our final policy .

(3) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2023 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) would result in operating outlier payments that would equal 5.1 percent of operating DRG payments. As discussed previously, once an outlier threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Therefore, our modified methodology produces two separate estimates of the percentage of capital outlier payments to total capital payments. One estimate is based on the shared threshold that was determined using all cases in the FY 2021 data. The other estimate is based on the shared threshold that was determined excluding COVID–19 cases in the FY 2021 data. As stated, we averaged these two estimates together to establish the final estimate of capital outlier payments to total capital payments for FY 2023. Therefore, based on this finalized methodology to average these two estimates, we estimate that capital outlier payments would equal 5.52 percent of capital payments based on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we are reducing the FY 2023 standardized amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the FY 2023 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.944837

*The adjustment factor for the capital Federal rate reflects this final rule's modified calculation and includes an adjustment to the estimated percentage of FY 2023 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III. A. 2 in the Addendum of this final rule.

We are applying the outlier adjustment factors to the FY 2023 payment rates after removing the effects of the FY 2022 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.224 or capital CCRs greater than 0.134 or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2022, and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable statewide average capital CCRs. As previously stated, the CCRs in Tables 8A and 8B would be used during FY 2023 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table

8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

(4) FY 2021 Outlier Payments

Our current estimate, using available FY 2021 claims data, is that actual outlier payments for FY 2021 were approximately 5.66 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2021, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2021. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2021 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier final rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2022 period would not be available until after September 30, 2022, we are unable to provide an estimate of actual outlier payments for FY 2022 based on FY 2022 claims data in the proposed rule and this final rule. We will provide an estimate of actual FY 2022 outlier payments in the FY 2024 IPPS/LTCH PPS proposed rule.

5. FY 2023 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2023. The standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 67.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we would apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the standardized amounts reflecting the applicable percentage increases for FY 2023.

The labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2023 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2022 national standardized amounts to the FY 2023 national standardized amounts. The second through fifth columns display the changes from the FY 2022 standardized amounts for each applicable FY 2023 standardized amount. The first row of the table shows the updated (through FY 2022) average standardized amount after restoring the FY 2022 offsets for outlier payments, geographic reclassification, rural demonstration, lowest quartile, and transition budget neutrality. The MS–DRG reclassification and recalibration, wage index, and stem cell acquisition budget neutrality factors are cumulative (that is, we have not restored the offsets). Accordingly, those FY 2022 adjustment factors have not been removed from the base rate in the following table. Additionally, for FY 2023 we have applied the budget neutrality factors for the lowest quartile hospital policy, described previously.

CHANGES FROM FY 2022 STANDARDIZED AMOUNTS TO THE FY 2023 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2023 Base Rate after removing:1. FY 2022 Geographic Reclassification Budget Neutrality (0.986741) 2. FY 2022 Operating Outlier Offset (0.949) 3. FY 2022 Rural Demonstration Budget Neutrality Factor (0.999361) 4. FY 2022 Lowest Quartile Budget Neutrality Factor (0.998029) 5. FY 2022 Transition Budget Neutrality Factor (0.999859)	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,431.41 Nonlabor (32.4%): $ 2,123.93	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,431.41 Nonlabor (32.4%): $ 2,123.93	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,431.41 Nonlabor (32.4%): $ 2,123.93	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,431.41 Nonlabor (32.4%): $ 2,123.93
	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 4,064.31 Nonlabor (38%): $ 2,491.03	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 4,064.31 Nonlabor (38%): $ 2,491.03	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 4,064.31 Nonlabor (38%): $ 2,491.03	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 4,064.31 Nonlabor (38%): $ 2,491.03
FY 2023 Update Factor	1.038	1.00725	1.02775	0.9970
FY 2023 MS-DRG Reclassification and Recalibration Budget Neutrality Factor Before Cap	1.000509	1.000509	1.000509	1.000509
FY 2023 Cap Policy MS-DRG Weight Budget Neutrality Factor	0.999764	0.999764	0.999764	0.999764
FY 2023 Wage Index Budget Neutrality Factor	1.000968	1.000968	1.000968	1.000968
FY 2023 Reclassification Budget Neutrality Factor	0.984399	0.984399	0.984399	0.984399
FY 2023 Lowest Quartile Budget Neutrality Factor	0.998146	0.998146	0.998146	0.998146
FY 2023 Cap Policy Wage Index Budget Neutrality Factor	0.999689	0.999689	0.999689	0.999689
FY 2023 RCH Demonstration Budget Neutrality Factor	0.998935	0.998935	0.998935	0.998935
FY 2023 Operating Outlier Factor	0.949	0.949	0.949	0.949
Adjustment for FY 2023 Required under Section 414 of Pub. L. 114-10 (MACRA)	1.005	1.005	1.005	1.005
National Standardized Amount for FY 2023 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (67.6/32.4)	**Labor: $4,310.00 Nonlabor $2,065.74**	**Labor: $4,182.32 Nonlabor: $2,004.54**	**Labor: $4,267.44 Nonlabor: $2,045.34**	**Labor: $4,139.76 Nonlabor: $1,984.15**
National Standardized Amount for FY 2023 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $3,952.96 Nonlabor: $2,422.78**	**Labor: $3,835.85 Nonlabor: $2,351.01**	**Labor: $3,913.92 Nonlabor: $2,398.86**	**Labor: $3,796.82 Nonlabor: $2,327.09**

B. Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the labor-related and nonlabor-related shares that we are using to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2023. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2023, as discussed in section IV.B.3. of the preamble of this final rule, we are applying a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this final rule, we discuss the data and methodology for the FY 2023 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described previously. To account for higher non-labor related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (at the same time as the update to the labor related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively). For FY 2022, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are continuing to use the same COLA factors in FY 2023 that were used in FY 2022 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. The following table lists the COLA factors for FY 2023.

FY 2023 Cost-of-Living Adjustment Factors (COLA): Alaska and Hawaii Hospitals

Area	FY 2022 - FY 2025
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Lastly, as we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), we intend to update the COLA factors based on our methodology every 4 years, at the same time as the update to the labor-related share of the IPPS market basket.

C. Calculation of the Prospective Payment Rates

1. General Formula for Calculation of the Prospective Payment Rates for FY 2023

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs, for FY 2023 equals the Federal rate (which includes uncompensated care payments). Under current law, the MDH program is effective for discharges on or before September 30, 2022. Therefore, under current law, the MDH program will expire at the end of FY 2022.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (which, as discussed in section VI.G. of the preamble of this final rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2022 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section.

2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier). We note that the formula specified below reflects our finalized policy to include the estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals in the computation of the outlier fixed-loss cost threshold.

Step 1—Determine the MS–DRG and MS–DRG relative weight (from Table 5) for each claim based on the ICD–10–CM diagnosis and ICD–10–PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

— Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))
— Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (l + IME + DSH)

Step 4—Determine operating and capital costs:

— Operating Costs = (Billed Charges × Operating CCR)
— Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

— Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)
— Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + Supplemental Payment for IHS/Tribal hospitals and Puerto Rico hospitals + New Technology Add-On Payment Amount
— Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)
— Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

— Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)
— Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor
— Capital Outlier Payment = (Capital Costs—Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. In addition, we add the uncompensated care payment to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments. Finally, as previously discussed, we are finalizing, beginning in FY 2023, to take into consideration the supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals when calculating outlier payments.

3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. (We note, under current law, the MDH program is effective for discharges on or before September 30, 2022. Therefore, under current law, the MDH program will expire at the end of FY 2022.)

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2023

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs are the following:

FY 2023	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	4.1	4.1	4.1	4.1
Adjustment for Failure to Submit Quality Data under section 1886(b)(3)(B)(viii) of the Act	0	0	-1.025	-1.025
Adjustment for Failure to be a Meaningful EHR User under section 1886(b)(3)(B)(ix) of the Act	0	-3.075	0	-3.075
Productivity Adjustment under section 1886(b)(3)(B)(xi) of the Act	-0.3	-0.3	-0.3	-0.3
Applicable Percentage Increase Applied to Standardized Amount	**3.8**	**0.725**	**2.775**	**-0.3**

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs, we refer readers to section V.B. of the preamble of this final rule.

In addition, because SCHs use the same MS–DRGs as other hospitals when they are paid based on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital specific-rate for an SCH is adjusted by the MS–DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of this Addendum. In addition, as discussed in section II.E.2.d of this final rule, we are establishing a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. As discussed in section II.E.2.d of this final rule, and consistent with our current methodology for implementing budget neutrality for DRG reclassification and recalibration of the relative weights, we are applying a budget neutrality adjustment to the standardized amount for all hospitals so that this 10-percent cap on relative weight reductions does not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. As mentioned previously, SCHs use the same MS–DRGs as other hospitals when they are paid based on the

hospital-specific rate. Therefore, we are establishing that the hospital specific-rate for an SCH would be adjusted by the MS–DRG 10-percent cap budget neutrality factor. The resulting rate is used in determining the payment rate that an SCH would receive for its discharges beginning on or after October 1, 2022. We note that, in this final rule, for FY 2023, we are not making a documentation and coding adjustment to the hospital specific-rate. We refer readers to section II.D. of the preamble of this final rule for a complete discussion regarding our policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix. We note, as mentioned previously, under current law, the MDH program is effective for discharges on or before September 30, 2022. Therefore, under current law, the MDH program will expire at the end of FY 2022.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2023

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we used to determine the capital Federal rate for FY 2023, which would be effective for discharges occurring on or after October 1, 2022.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2023

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2023. In particular, we explain why the FY 2023 capital Federal rate would increase approximately 2.36 percent, compared to the FY 2022 capital Federal rate. As discussed in the impact analysis in Appendix A to this final rule, we estimate that capital payments per discharge will increase approximately 0.6 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

As discussed in section I.F. of the preamble to this final rule, we are finalizing our proposal to use FY 2021 data for purposes of FY 2023 IPPS ratesetting. Consistent with this policy, for this final rule we are finalizing our proposal to use claims from the March 2022 update of the FY 2021 MedPAR file for purposes of calculating the budget neutrality adjustment factors for changes resulting from the annual DRG reclassification and recalibration and changes in the GAF. However, as we also discuss in section I.F. of the preamble to this final rule, we are finalizing certain modifications to our usual methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals in FY 2023 as compared to FY 2021. First, we are modifying the calculation of the FY 2023 MS–DRG relative weights by first calculating two sets of weights, one including and one excluding COVID–19 claims in the FY 2021 data, and then averaging the two sets of relative weights to determine the FY 2023 MS–DRG relative weight values (as described in greater detail in section II.E. of the preamble to this final rule). Second, we are modifying our methodology for determining the FY 2023 outlier fixed-loss amount for IPPS cases by using charge inflation factors and CCR adjustment factors based on the last 1-year period prior to the COVID–19 PHE. We also are modifying our methodology for determining the FY 2023 outlier fixed-loss amount for IPPS cases by establishing the fixed-loss amount as an average of fixed-loss amounts calculated including and excluding COVID–19 claims in the FY 2021 data. Lastly, we are modifying our methodology for determining the FY 2023 outlier fixed-loss amount for IPPS cases by including the increases in payments to COVID–19 cases provided by the CARES Act in the calculation of the fixed-loss amount. The modifications we have made to our methodology for determining the FY 2023 outlier fixed-loss amount for IPPS cases are discussed in greater detail in section II.A.4. of the Addendum to this final rule.

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The update factor for FY 2023 under that framework is 2.5 percent based on a projected 2.5 percent increase in the 2018-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of 0.0 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2023 CIPI projection in that same section of this Addendum. In this final rule, we describe the policy adjustments that we applied in the update framework for FY 2023.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons—

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2023, we project a 1.0 percent total increase in the case-mix index. We estimated that the real case-mix increase would equal 1.0 percent for FY 2023. The net adjustment for change in case-mix is the difference between the projected real increases in case mix and the projected total increase in case mix. Therefore, as proposed, the net adjustment for case-mix change in FY 2023 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG

reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, for this FY 2023 IPPS/LTCH PPS final rule, we have the FY 2021 MedPAR claims data available to evaluate the effects of the FY 2021 DRG reclassification and recalibration as part of our update for FY 2023. We assume for purposes of this adjustment, that the estimate of FY 2021 DRG reclassification and recalibration would result in no change in the case-mix when compared with the case mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, as proposed, we are making a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2023.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is greater than 0.25 percentage point in absolute terms. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of −0.1 percentage point was calculated for the FY 2021 update, for which there are historical data. That is, current historical data indicated that the forecasted FY 2021 CIPI (1.1 percent) used in calculating the FY 2021 update factor is 0.1 percentage point higher than actual realized price increases (1.0 percent). As this does not exceed the 0.25 percentage point threshold, as proposed we are not making an adjustment for forecast error in the update for FY 2023.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this final rule, as proposed, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2023 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2023, we are using an intensity measure that is based on an average of cost-per-discharge data from the 5-year period beginning with FY 2016 and extending through FY 2020. Based on these data, we estimated that case-mix constant intensity declined during FYs 2016 through 2020. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity would decline during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2023. Therefore, as proposed, we are making a 0.0 percentage point adjustment for intensity in the update for FY 2023.

Earlier, we described the basis of the components we used to develop the 2.5 percent capital update factor under the capital update framework for FY 2023, as shown in the following table.

FY 2023 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	2.5
Intensity:	0.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	-1.0
Real Across DRG Change	1.0
Subtotal	0.0
Effect of FY 2021 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	2.5

*The capital input price index represents the 2018-based CIPI.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2023, we have incorporated the estimated outlier reconciliation payment amounts into the outlier threshold model, as we did for FY 2022. (For more details on our incorporation of the estimated outlier reconciliation payment amounts into the outlier threshold model, please see section II.A. of this Addendum to this final rule.)

For FY 2022, we estimated that outlier payments for capital-related PPS payments would equal 5.29 percent of inpatient capital-related payments based on the capital Federal rate. As discussed previously and in section II.A.4.j. of the Addendum to this final rule, we are modifying our methodology for determining the FY 2023 outlier threshold for IPPS cases. For FY 2023, this threshold is being determined as an average of the thresholds calculated when including and excluding COVID–19 cases in the FY 2021 claims data. As also discussed in section

II.A., this modification results in two separate estimates of outlier payments for capital related costs as a percentage of inpatient capital-related payments (prior to taking into account projected capital outlier reconciliation payments). One estimate is based on the outlier threshold that was calculated using all cases (that is including COVID–19 cases). The other estimate is based on the outlier threshold that was calculated excluding COVID–19 cases. Consistent with our modification to average the outlier thresholds in determining the final FY 2023 outlier threshold, we are estimating the capital outlier percentage for FY 2023 as the average of these two estimates. Accordingly, as discussed in more detail in section II.A.4.j. of the Addendum to this final rule, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs will equal 5.53 percent of inpatient capital-related payments based on the capital Federal rate in FY 2023.

Using the methodology outlined in section II.A.4.j.(2). of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments will decrease FY 2023 aggregate estimated capital outlier payments by 0.01 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 5.52 percent (5.53 percent—0.01 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2023. Accordingly, we applied an outlier adjustment factor of 0.9448 in determining the capital Federal rate for FY 2023. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2023 will be higher than the percentage for FY 2022.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The FY 2023 outlier adjustment of 0.9448 is a −0.24 percent change from the FY 2022 outlier adjustment of 0.9471. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2023 is 0.9976 (0.9448/0.9471) so that the outlier adjustment will decrease the FY 2023 capital Federal rate by approximately −0.24 percent compared to the FY 2022 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.G.3. of the preamble of this final rule, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to help reduce wage index disparities between high and low wage index hospitals by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index. We stated our intention that this policy will be effective for at least 4 years, beginning in FY 2020. As discussed in section III.G.3 of the preamble of this final rule, this policy was applied in FYs 2020, 2021, and 2022, and will continue to apply in FY 2023 as we proposed. In addition, in FYs 2020 and 2021, we placed a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year (see (84 FR 42336 through 42338) and (85 FR 58753 through 58755)). In FY 2022, we finalized a policy that for hospitals that received the transition in FY 2021 (that is hospitals that received a 5 percent cap on their FY 2021 wage index), we continued a wage index transition for FY 2022 under which we applied a 5-percent cap on any decrease in the hospital's wage index compared to its wage index for FY 2021 (86 FR 45164 through 45165). Beginning in FY 2023, as discussed in section III.N. of the preamble to this final rule, we finalized a permanent 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index will not be less than 95 percent of its final wage index for the prior FY.

As we discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42638 through 42639), we augmented our historical methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those wage index changes on the GAFs. Specifically, we established a 2-step methodology, under which we first calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy, consistent with our historical GAF budget neutrality factor methodology. In the second step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to our policy to increase the wage index for hospitals with a wage index value below the 25th percentile wage index and our policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year. In this section of this Addendum, we refer to these two policies as the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. We further note that in this section of this Addendum, for this final rule, we also refer to the permanent cap on wage index decreases beginning in FY 2023 as the 5-percent cap on wage index decreases policy.

The budget neutrality factors applied for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are built permanently into the capital Federal rate; that is, they are applied cumulatively in determining the capital Federal rate. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45552), we finalized our proposal to not permanently apply the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases such that they would not be applied cumulatively in determining the capital Federal rate. We believe this is more technically appropriate because the GAFs with the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policies applied from the previous year are not used in the budget neutrality factor calculations for the current year. Accordingly, and consistent with this approach, prior to calculating the GAF budget neutrality factors for FY 2023, we removed from the capital Federal rate the budget neutrality factor applied in FY 2022 for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. Specifically, we divided the capital Federal rate by the FY 2022 budget neutrality factor of 0.9974 (86 FR 45552). We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45552) for additional discussion on our policy of removing the prior year budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases from the capital Federal rate.

In light of the changes to the wage index and other wage index policies for FY 2023 discussed previously, which directly affect the GAF, we continue to compute a budget neutrality adjustment for changes in the GAFs in two steps. We discuss our 2-step calculation of the GAF budget neutrality factors for FY 2023 as follows.

To determine the GAF budget neutrality factors for FY 2023, we first compared estimated aggregate capital Federal rate payments based on the FY 2022 MS–DRG classifications and relative weights and the FY 2022 GAFs to estimated aggregate capital Federal rate payments based on the FY 2022 MS–DRG classifications and relative weights and the FY 2023 GAFs without incorporating the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. To achieve budget neutrality for these changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 1.0008 for FY 2023. Next, we compared estimated aggregate capital Federal rate payments based on the FY 2023 GAFs with and without the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases policy. For this calculation, estimated aggregate capital Federal rate payments were calculated using the FY 2023 MS–DRG classifications and relative weights (after application of the 10-percent cap discussed later in this section of the Addendum) and the FY 2023 GAFs (both with and without the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy). (We note, for this calculation the GAFs included the imputed floor, out-migration and Frontier state adjustments.) To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy on the FY 2023 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9972. As discussed earlier in this section of the Addendum, the budget neutrality factor for the lowest quartile hospital wage index adjustment factor and the 5-percent cap on

wage index decreases is not permanently built into the capital Federal rate. Consistent with this, we present the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases calculated under the second step of this 2-step methodology separately from the other budget neutrality factors in the discussion that follows, and this factor is not included in the calculation of the combined GAF/DRG adjustment factor described later in this section of the Addendum.

In section II.E.2. of the preamble to this final rule, we finalized our proposal to apply a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given year. Consistent with our current methodology for adjusting the capital standard Federal rate to ensure that the effects of the annual DRG reclassification and the recalibration of DRG weights are budget neutral under § 412.308(c)(4)(ii), as we proposed, we are applying an additional budget neutrality factor to the capital standard Federal rate so that the 10-percent cap on decreases in an MS–DRG's relative weight is implemented in a budget neutral manner. Specifically, in light of this provision, as proposed, we are augmenting our historical methodology for computing the budget neutrality factor for the annual DRG reclassification and recalibration by computing a budget neutrality adjustment for the annual DRG reclassification and recalibration in two steps. We first calculate a budget neutrality factor to account for the annual DRG reclassification and recalibration prior to the application of the 10-percent cap on MS–DRG relative weight decreases. Then we calculate an additional budget neutrality factor to account for the application of the 10-percent cap on MS–DRG relative weight decreases.

To determine the DRG budget neutrality factors for FY 2023, we first compared estimated aggregate capital Federal rate payments based on the FY 2022 MS–DRG classifications and relative weights to estimated aggregate capital Federal rate payments based on the FY 2023 MS–DRG classifications and relative weights prior to the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were calculated using the FY 2023 GAFs without the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. The incremental adjustment factor for DRG classifications and changes in relative weights prior to the application of the 10-percent cap is 1.0006. Next, we compared estimated aggregate capital Federal rate payments based on the FY 2023 MS–DRG classifications and relative weights prior to the application of the 10-percent cap to estimated aggregate capital Federal rate payments based on the FY 2023 MS–DRG classifications and relative weights after the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were also calculated using the FY 2023 GAFs without the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. The incremental adjustment factor for the application of the 10-percent cap on relative weight decreases is 0.9998. Therefore, to achieve budget neutrality for the FY 2023 MS–DRG reclassification and recalibration (including the 10-percent cap), based on the calculations described previously, we are applying an incremental budget neutrality adjustment factor of 1.0004 (1.0006 × 0.9998) for FY 2023 to the capital Federal rate. We note that all the values are calculated with unrounded numbers.

The incremental adjustment factor for the FY 2023 MS–DRG reclassification and recalibration (1.0004) and for changes in the FY 2023 GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (1.0008) is 1.0012 (1.0004 × 1.0008). This incremental adjustment factor is built permanently into the capital Federal rates. To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy on the FY 2023 GAFs, as described previously, we calculated a budget neutrality adjustment factor of 0.9972 for FY 2023. We refer to this budget neutrality factor for the remainder of this section as the lowest quartile/cap adjustment factor.

We applied the budget neutrality adjustment factors described previously to the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are determined separately. Under the capital IPPS, there is a single budget neutrality adjustment factor for changes in the GAF that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy. In addition, there is no adjustment for the effects that geographic reclassification, the lowest quartile hospital wage index adjustment, or the 5-percent cap on wage index decreases policy described previously have on the other payment parameters, such as the payments for DSH or IME.

The incremental GAF/DRG adjustment factor of 1.0012 accounts for the MS–DRG reclassifications and recalibration (including application of the 10-percent cap on relative weight decreases) and for changes in the GAFs that result from updates to the wage data, the effects on the GAFs of FY 2023 geographic reclassification decisions made by the MGCRB compared to FY 2022 decisions, and the application of the rural floor policy. The lowest quartile/cap adjustment factor of 0.9972 accounts for changes in the GAFs that result from our policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index and the 5-percent cap on wage index decreases policy. However, these factors do not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Capital Federal Rate for FY 2023

For FY 2022, we established a capital Federal rate of $472.59 (86 FR 45553, as corrected in 86 FR 58026). We are establishing an update of 2.5 percent in determining the FY 2023 capital Federal rate for all hospitals. As a result of this update and the budget neutrality factors discussed earlier, we are establishing a national capital Federal rate of $483.76 for FY 2023. The national capital Federal rate for FY 2023 was calculated as follows:

- The FY 2023 update factor is 1.025; that is, the update is 2.5 percent.
- The FY 2023 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights (including application of the 10-percent cap on relative weight decreases) and changes in the GAFs that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy is 1.0012.
- The FY 2023 lowest quartile/cap budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the GAFs that result from our policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index and the 5-percent cap on wage index decreases policy is 0.9972.
- The FY 2023 outlier adjustment factor is 0.9448.

We are providing the following chart that shows how each of the factors and adjustments for FY 2023 affects the computation of the FY 2023 national capital Federal rate in comparison to the FY 2022 national capital Federal rate. The FY 2023 update factor has the effect of increasing the capital Federal rate by 2.5 percent compared to the FY 2022 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of increasing the capital Federal rate by 0.12 percent. The FY 2023 lowest quartile/cap budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.02 percent compared to the FY 2022 capital Federal rate. The FY 2023 outlier adjustment factor has the effect of decreasing the capital Federal rate by 0.24 percent compared to the FY 2022 capital Federal rate. The combined effect of all the changes will increase the national capital Federal rate by approximately 2.36 percent, compared to the FY 2022 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2022 CAPITAL FEDERAL RATE AND THE FY 2023 CAPITAL FEDERAL RATE

	FY 2022	FY 2023	Change	Percent Change
Update Factor[1]	1.0080	1.0250	1.0250	2.50
GAF/DRG Adjustment Factor[1]	1.0004	1.0012	1.0012	0.12
Quartile/Cap Adjustment Factor[2]	0.9974	0.9972	0.9998	-0.02
Outlier Adjustment Factor[3]	0.9471	0.9448	0.9976	-0.24
Capital Federal Rate	$472.59	$483.76	1.0236	2.36[4]

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rate. Thus, for example, the incremental change from FY 2022 to FY 2023 resulting from the application of the 1.0012 GAF/DRG budget neutrality adjustment factor for FY 2023 is a net change of 0.0012 (or 0.12 percent).

[2] The lowest quartile/cap budget neutrality adjustment factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2023 lowest quartile/cap budget neutrality adjustment factor is 0.9972/0.9974 or 0.9998 (or -0.02 percent).

[3] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2023 outlier adjustment factor is 0.9448/0.9471 or 0.9976 (or -0.24 percent).

[4] Percent change may not sum due to rounding.

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2023

For purposes of calculating payments for each discharge during FY 2023, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The outlier threshold for FY 2023 is in section II.A. of this Addendum. For FY 2023, a case will qualify as a cost outlier if the cost for the case is greater than the prospective payment rates for the MS–DRG plus IME and DSH payments (including the empirically justified Medicare DSH payment and the estimated uncompensated care payment), any add-on payments for new technology, and, as we finalized beginning in FY 2023, the estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals (as discussed in section IV.E. of the preamble of this final rule), plus the fixed-loss amount of $38,859.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. For this final rule, we are using the IPPS operating and capital market baskets that reflect a 2018 base year. For a complete discussion of this rebasing, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45213).

2. Forecast of the CIPI for FY 2023

Based on IHS Global Inc.'s second quarter 2022 forecast, for this final rule, we are forecasting the 2018-based CIPI to increase 2.5 percent in FY 2023. This reflects a projected 2.9 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 6.7 percent increase in other capital expense prices in FY 2023, partially offset by a projected 1.7 percent decline in vintage-weighted interest expense prices in FY 2023. The weighted average of these three factors produces the forecasted 2.5 percent increase for the 2018-based CIPI in FY 2023. As proposed, we are using the more recent data available for this final rule to determine the FY 2023 increase in the 2018-based CIPI for this final rule.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2023

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

In the FY 2023 IPPS/LTCH PPS proposed rule, based on IGI's 2021 fourth quarter forecast, we estimated the 2018-based IPPS operating market basket update for FY 2023 to be 3.1 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2023. More recent data did subsequently become available. Thus, for this FY 2023 IPPS/LTCH PPS final rule, based on IGI's second quarter 2022 forecast, the FY 2023 rate-of-increase percentage that will be applied to the FY 2022 target amounts in order to calculate the FY 2023 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals is 4.1 percent, in accordance with the applicable regulations at 42 CFR 413.40.

IRFs and rehabilitation distinct part units, IPFs and psychiatric units, and LTCHs are

excluded from the IPPS and paid under their respective PPSs. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VIII. of the preamble and section V. of the Addendum of this final rule for the changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2023. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

We received no comments on this proposal and therefore are finalizing this provision without modification.

V. Changes to the Payment Rates for the LTCH PPS for FY 2023

A. LTCH PPS Standard Federal Payment Rate for FY 2023

1. Overview

In section VIII. of the preamble of this final rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2023.

Under § 412.523(c)(3) of the regulations, for FY 2012 and subsequent years, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II) and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xvii)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as discussed in section VIII.C.2. of the preamble of this final rule. This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VIII.C.2. of the preamble of this final rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the FY 2023 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2023, as we proposed, we are applying the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2023, we are also making certain regulatory adjustments, consistent with past practices. Specifically, in determining the FY 2023 LTCH PPS standard Federal payment rate, as we proposed, we are applying a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data and labor-related share) as discussed in section V.B.5. of this Addendum to this final rule.

In this final rule, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 3.8 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 4.1 percent less the productivity adjustment of 0.3 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are applying an update factor of 1.038 to the FY 2022 LTCH PPS standard Federal payment rate of $44,713.67 to determine the FY 2023 LTCH PPS standard Federal payment rate. Also, in accordance with § 412.523(c)(3)(xvii) and (c)(4), we are required to reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for LTCHs that fail to submit the required quality reporting data for FY 2023 as required under the LTCH QRP. Therefore, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1.8 percent (that is, an update factor of 1.018) for FY 2023 for LTCHs that fail to submit the required quality reporting data for FY 2023 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we are applying an area wage level budget neutrality factor to the FY 2023 LTCH PPS standard Federal payment rate of 1.0004304, based on the best available data at this time, to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index (including application of the 5-percent cap on wage index decreases, discussed later in this section of this final rule), and labor-related share) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are establishing an LTCH PPS standard Federal payment rate of $46,432.77 (calculated as $44,713.67 × 1.038 × 1.0004304) for FY 2023. For LTCHs that fail to submit quality reporting data for FY 2023, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $45,538.11 (calculated as $44,713.67 × 1.018 × 1.0004304) for FY 2023.

B. Adjustment for Area Wage Levels Under the LTCH PPS for FY 2023

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The FY 2023 LTCH PPS standard Federal payment rate wage index values that will be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2022, through September 30, 2023, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website.

2. Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB, and a ''rural area'' is defined as any area outside of an urban area (75 FR 37246).

The geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the Core Based Statistical Areas (CBSAs) established by OMB, which are based on the 2010 decennial census data. In general, the current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. (We note we have adopted minor revisions and updates in the years between the decennial censuses.) We adopted these labor market area delineations because they were at that time based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believed that these OMB delineations would ensure that the LTCH PPS area wage level adjustment most appropriately accounted for and reflected the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical

areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. OMB Bulletin No. 17–01, issued August 15, 2017, established the delineations for the Nation's statistical areas, and the corresponding changes to the CBSA-based labor market areas were adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731). A copy of this bulletin may be obtained on the website at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2017/b-17-01.pdf*.

On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. Historically OMB bulletins issued between decennial censuses have only contained minor modifications to CBSA delineations based on changes in population counts. However, OMB's 2010 Standards for Delineating Metropolitan and Micropolitan Standards created a larger mid-decade redelineation that takes into account commuting data from the American Commuting Survey. As a result, the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the CBSAs than are typical for OMB bulletins issued between decennial censuses. We adopted the updates set forth in OMB Bulletin No. 18–04 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59050 through 59051). A copy of the September 14, 2018 OMB Bulletin No. 18–04, may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04, which was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*.) In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area and one new component of an existing Combined Statistical Area. After reviewing OMB Bulletin No. 20–01, we determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the CBSA-based labor market area delineations used under the LTCH PPS. Therefore, we adopted the updates set forth in OMB Bulletin No. 20–01 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45556 through 45557) consistent with our general policy of adopting OMB delineation updates; however, the LTCH PPS area wage level adjustment was not altered as a result of adopting the updates because the CBSA-based labor market area delineations were the same as the CBSA-based labor market area delineations adopted in the FY 2021 IPPS/LTCH PPS final rule based on OMB Bulletin No. 18–04 (85 FR 59050 through 59051).

We believe the CBSA-based labor market area delineations, as established in OMB Bulletin 20–01, ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). Therefore, for FY 2023, we did not propose any changes to the CBSA-based labor market area delineations as established in OMB Bulletin 20–01 and adopted in the FY 2022 IPPS/LTCH final rule.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on their website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html*. We believe that it is important to use the latest counties or county equivalent entities to properly crosswalk LTCHs from a county to a CBSA for purposes of the wage indexes used under the LTCH PPS. Based on the latest information included in the Census Bureau's website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.2010.html*, the Census Bureau has made the following updates to the Federal Information Processing Series (FIPS) codes for counties or county equivalent entities:

- Chugach Census Area, AK (FIPS State County Code 02–063) and Copper River Census Area, AK (FIPS State County Code 02–066) were created from former Valdez-Cordova Census Area (02–261) which was located in CBSA 02. The CBSA code for these two new county equivalents remains 02.

We believe using the latest FIPS codes allows us to maintain a more accurate and up-to-date payment system that reflects population shifts and labor market conditions. Therefore, we are adopting these FIPS code updates listed previously, effective October 1, 2022. We note that while the county update changes listed previously changed the county names, the CBSAs to which these counties map did not change from the prior counties. We also note that there are currently no LTCHs located in these counties. However, if an LTCH were to open in one of these counties, there would be no impact or change to the LTCH for purposes of the LTCH PPS wage indexes as a result of our implementation of these FIPS code updates. We are publishing, as a supplemental file to this final rule, an updated county-to-CBSA crosswalk that reflects this provision.

3. Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting a 2009-based LTCH market basket. In addition, for FY 2013 through FY 2016, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) For FY 2017, we rebased and revised the 2009-based LTCH market basket to reflect a 2013 base year. In addition, for FY 2017 through FY 2020, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2013-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57096).) Then, effective for FY 2021, we rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2017-based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).)

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28683 through 26864), consistent with our historical practice, we proposed that the LTCH PPS labor-related share for FY 2023 is the sum of the FY 2023 relative importance of each labor-related cost category in the LTCH market basket using the most recent available data. Specifically, we proposed that the labor-related share for FY 2023 would continue to include the sum of the labor-related portion of operating costs from the 2017-based LTCH market basket (that is, the sum of the FY 2023 relative importance shares of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the relative importance of Capital-Related cost weight from the 2017-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2017) and FY 2023. Based on IHS Global Inc.'s fourth quarter 2021 forecast of the 2017-based LTCH market basket, the sum of the FY 2023 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, & Repair Services; and All Other: Labor-Related Services was 64.0 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46

percent (that is, the same percentage applied to the 2009-based and 2013-based LTCH market baskets). Since the FY 2023 relative importance for capital-related costs was 9.2 percent based on IHS Global Inc.'s fourth quarter 2021 forecast of the 2017-based LTCH market basket, we took 46 percent of 9.2 percent to determine the labor-related share of capital-related costs for FY 2023 of 4.2 percent. Therefore, in the IPPS/LTCH PPS proposed rule (87 FR 28684), we proposed a total labor-related share for FY 2023 of 68.2 percent (the sum of 64.0 percent for the operating costs and 4.2 percent for the labor-related share of capital-related costs). We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the relative importance of each labor-related cost category of the 2017-based LTCH market basket), we would use such data, if appropriate, to determine the FY 2023 LTCH PPS labor-related share.

Comment: A commenter opposed the increase in labor-related share for LTCHs for FY 2023. The commenter noted that the increase in labor-related share adversely impacts any LTCH with a wage index of less than 1.0. According to the commenter, limiting the increase would help mitigate the growing disparity between high-wage and low-wage states.

Response: We thank the commenter for the feedback. As noted previously, effective for FY 2021, we rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2017-based LTCH market basket using the most recent available data (85 FR 58909 through 58926). We continue to believe that this approach is the most appropriate methodology for determining the labor-related portion of the LTCH PPS standard Federal payment rate. We note that the proposed labor related share of 68.2 percent, which was based on IHS Global Inc's fourth quarter 2021 forecast of the 2017-based LTCH market basket, has been updated to reflect IHS Global Inc's second quarter 2022 forecast, and that this update, resulting in a labor related share of 68.0 percent, is a slightly smaller increase over the labor share from FY 2022, which was 67.9 percent.

After consideration of public comments, we are finalizing the FY 2023 labor-related share using the most recently available data. Based on IHS Global Inc.'s second quarter 2022 forecast of the 2017-based LTCH market basket, the sum of the FY 2023 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, & Repair Services; and All Other: Labor-Related Services is 63.8 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (that is, the same percentage applied to the 2009-based and 2013-based LTCH market baskets). Since the FY 2023 relative importance for capital-related costs is 9.1 percent based on IHS Global Inc.'s second quarter 2022 forecast of the 2017-based LTCH market basket, we took 46 percent of 9.1 percent to determine the labor-related share of capital-related costs for FY 2023 of 4.2 percent. Therefore, we are finalizing a total labor-related share for FY 2023 of 68.0 percent (the sum of 63.8 percent for the operating costs and 4.2 percent for the labor-related share of capital-related costs).

4. Wage Index for FY 2023 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider. As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also employ a policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2023 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, as we proposed, we are continuing to employ our historical practice of using the same data we used to compute the FY 2023 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final rule (that is, wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2019) because these data are the most recent complete data available.

In addition, as we proposed, we computed the FY 2023 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the proposed labor market area delineations as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. As we proposed, we also continued to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2023 as we proposed, we continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2019 IPPS wage data that we used to determine the FY 2023 LTCH PPS area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with our existing methodology, we calculated the FY 2023 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this final rule.

Based on the FY 2019 IPPS wage data that we used to determine the FY 2023 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a LTCH PPS wage index value for rural areas with no IPPS wage data for FY 2023. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future.

5. Permanent Cap on Wage Index Decreases

a. Permanent Cap on LTCH PPS Wage Index Decreases

In the past, we have proposed and finalized temporary transition policies to mitigate significant changes to payments due to changes to the LTCH PPS wage index, particularly when adopting changes that have large negative impacts on an LTCH's payments. In the FY 2021 IPPS/LTCH final rule (85 FR 59052), we implemented a 5-percent cap on any decrease in an LTCH's wage index from the LTCH's final wage index in FY 2020, so that the hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. We implemented this policy to mitigate potential negative consequences of finalizing the adoption of revised CBSA delineations announced in OMB Bulletin 18–04 for FY 2021. In particular, we acknowledged that a significant portion of Medicare LTCH PPS payments are adjusted by the wage index and that some changes in OMB delineations destabilized payments to LTCHs. We stated our belief that applying the 5-percent cap to all wage index decreases for FY 2021 provided an adequate safeguard against significant payment reductions related to the adoption of the revised CBSAs and that it would improve stability and predictability in payment levels to LTCHs. We applied a budget neutrality adjustment to the FY 2021 standard Federal payment rate to achieve budget neutrality for this policy (85 FR 59053).

Although we did not propose or implement a cap on wage index decreases for LTCH's in FY 2022, we acknowledged that some commenters requested that we extend the FY 2021 transition policy, citing the continuing impact of changes related to the OMB updates and the unprecedented nature of the ongoing COVID–19 PHE. In response to those comments, we reiterated that our policy principles with regard to the wage index include generally using the most current data and information available and providing that

data and information, as well as addressing significant year-over-year variations in Medicare payments in notice and comment rulemaking.

For FY 2023, we further considered comments received during the FY 2022 rulemaking, including requests for a broader, permanent wage index policy to mitigate unpredictable changes in payments to LTCHs resulting from large wage index decreases. We recognize that changes to the wage index have the potential to create instability and significant negative impacts on certain providers even when we have not adopted specific changes to wage index policy. That is, year to year fluctuations in an area's wage index can occur due to external factors that can be difficult for an LTCH to predict and are often outside an LTCH's ability to directly control, such as the COVID–19 PHE. We recognize that predictability in Medicare payments is important to enable hospitals to budget and plan their operations. For LTCHs, in particular, we further recognize that a significant portion of Medicare LTCH PPS payments are adjusted by the wage index and that a large decrease from one year to the next can have significant implications for LTCH payments.

For these reasons, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28684 through 28685), we proposed, beginning with FY 2023, to apply a permanent 5-percent cap on any decrease to an LTCH's wage index from its wage index in the prior year. In the proposed rule, we stated our belief that a 5-percent reduction is an appropriate threshold to mitigate large negative financial impacts on hospitals and limit the magnitude of the associated proposed budget neutrality adjustment (discussed later in section V.A.5. of the Addendum). Typical year-to-year variations in the LTCH wage index have historically been within 5 percent, and we expect this will continue to be the case in future years. Because providers typically experience some level of wage index fluctuation, we stated our belief that applying a 5-percent cap on all wage index decreases each year, regardless of the reason for the decrease, would effectively mitigate instability and increase predictability in LTCH PPS payments due to any significant wage index decreases.

In the proposed rule, we stated our belief that this proposed policy of applying a permanent cap to wage index decreases would provide greater predictability to LTCHs. That is, the policy would smooth year-to-year changes in LTCHs' wage indexes and provide for increased predictability in their wage index and thus their LTCH PPS payments. We also stated our belief that our proposed permanent policy would mitigate significant payment reductions due to changes in wage index policy, such as the adoption of the revised CBSAs in FY 2021, thereby eliminating the need for one-off temporary transition adjustments to wage index levels in the future. Because applying a 5-percent cap on all wage index decreases would generally represent a small overall impact on the adjustment for area wage levels, we stated our belief that the 5-percent cap would not distort the integrity of the wage index as a relative measure of the value of labor in a labor market area.

Furthermore, consistent with the requirement at § 412.525(c)(2), that changes to area wage level adjustments are made in a budget neutral manner, we proposed that the 5-percent cap on the decrease on an LTCH's wage index would not result in any change in estimated aggregate LTCH PPS payments by including the application of this policy in the determination of the area wage level budget neutrality factor that is applied to the standard Federal payment rate, as is discussed later in section V.B.6. of the Addendum to the final rule.

We proposed that an LTCH's wage index cap adjustment would be determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. We proposed that new LTCHs that became operational during the prior Federal fiscal year would be subject to the LTCH PPS wage index cap. For example, if an LTCH begins operations on July 1, 2022 and is paid its area wage index of 0.9000 for the remainder of FY 2022, its FY 2023 wage index would be capped at 95 percent of that value and could not be lower than 0.8550 (0.95×0.9000). However, for newly opened LTCHs that become operational on or after the first day of the fiscal year to which this final rule would apply, we proposed that these LTCHs would not be subject to the LTCH PPS wage index cap since they were not paid under the LTCH PPS in the prior year. These LTCHs would receive the calculated wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage cap. For example, a hospital that opens on December 1, 2022 would not be eligible for a capped wage index in FY 2023, as it was not paid a wage index during FY 2022.

Comment: We received several comments expressing support for our proposed permanent 5-percent cap on any decrease to an LTCH's wage index from its wage index in the prior year beginning with FY 2023. Commenters generally agreed that the cap would help mitigate significant payment decreases and provide stability and predictability to LTCH payments. Some commenters encouraged CMS to apply this general principle of increasing stability to other aspects of LTCH payment policies.

Response: We appreciate the support for our proposal. We agree with commenters about the importance of stability and predictability in LTCH PPS payments. We will continue to consider additional policy options to achieve this objective in future rulemaking.

Comment: MedPAC supported our proposal to cap LTCH's wage index decreases at 5 percent, but suggested also applying a cap to increases of more than 5 percent.

Response: We appreciate MedPAC's suggestion that CMS should apply a cap on wage index increases greater than 5 percent. However, as we discussed in the proposed rule, the purpose of the proposed policy is to help mitigate the significant negative impacts of certain wage index changes. We believe applying a 5-percent cap on all wage index decreases would support increased predictability about LTCH PPS payments for providers, enabling them to more effectively budget and plan their operations. That is, we believe that a provider would be able to more effectively budget and plan when there is predictability about its expected minimum level of LTCH PPS payments in the upcoming fiscal year. We did not propose to limit wage index increases because we do not believe such a policy is needed to enable LTCHs to more effectively budget and plan their operations. So, we believe it is appropriate for providers that would experience an increase in their wage index value to receive the wage index value that most accurately reflects the labor costs in that area.

Comment: A number of commenters disagreed with our proposal to implement the proposed 5-percent cap on wage index decreases in a budget neutral manner and maintained that CMS has the statutory authority to implement the proposed policy in a non-budget neutral manner. Some of these commenters indicated that their support of the cap was conditional on CMS not implementing the cap in a budget neutral manner.

Response: While CMS's statutory authority is broad, we continue to believe it is appropriate to implement this policy in a budget neutral manner which is consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner. That is, we continue to believe that changes to area wage level adjustments, including the proposed 5-percent cap on the decrease on an LTCH's wage index, should not result in any change in estimated aggregate LTCH PPS payments. We also anticipate that in the absence of proposed policy changes most LTCHs will not experience year-to-year wage index declines greater than 5 percent in any given year and that the overall budget neutrality adjustments associated with the policy will be relatively small and would not create volatility in LTCH PPS payments.

Comment: A commenter recommended that CMS retroactively apply the 5-percent cap policy to the FY 2022 wage index for LTCHs that experienced wage index decreases due to their transition to a new CBSA based on the new OMB delineations that were finalized for FY 2021.

Response: As noted previously, in FY 2021, we implemented a transition to mitigate any negative effects of wage index changes by applying a 5-percent cap on any decrease in an LTCH's wage index from the LTCH's final wage index in FY 2020; we indicated that no cap would be applied to the reduction in the second year, FY 2022. In the FY 2023 IPPS/LTCH PPS proposed rule, we did not propose to modify that transition policy to extend the transition period for FY 2022. We have historically implemented transitions of limited duration to address CBSA changes due to substantial updates to OMB delineations. In accordance with our policy principles that we use the most updated data and information available with regard to the wage index, we proposed that the FY 2023 5-percent cap wage index policy would be prospective to mitigate any significant decreases beginning in FY 2023.

Comment: Some commenters disagreed with our proposal to apply the 5-percent cap on decreases to an LTCH's wage index only to existing hospitals; that is, hospitals that were already operational on the last day of the prior Federal fiscal year. The commenters stated that this policy would create unnecessary inequity in Medicare payments for hospitals in the same market. They encouraged CMS to apply the same area wage index value for new and existing hospitals.

Response: We appreciate the commenters' concerns about equity and fairness. As we have stated, however, the primary purpose of applying a 5-percent cap on decreases to an LTCH's wage index is to support predictability about LTCH payments, mitigate financial instability from one year to the next, and enable LTCHs to more effectively budget and plan their operations. LTCHs that were not operational on the last day of the prior Federal fiscal year could not experience LTCH PPS payment decreases relative to the prior year since they would have received no LTCH PPS payments in the prior year. In addition, we do not expect that there would be many LTCHs in this situation. There are few newly created LTCHs, in general, and even fewer that will open in an area that is receiving an adjustment under the policy. Finally, we note that any differential in the wage index related to a newly operational LTCH and an existing LTCH in the same labor market area will generally be limited to a single year, since typical year-to-year variations in the LTCH wage index have historically been, and we expect will continue to be, within 5 percent.

Comment: A commenter, while supportive of the proposed 5-percent cap on wage index decreases, believes it does not correct for an ongoing problem with the range in wage index values amongst LTCHs. This commenter believes the range in wage index values is too large and that CMS should establish an annual cap that would be placed on CBSAs with high wage index values. Furthermore, the same commenter believes that LTCHs should have the option to reclassify to a different CBSA as is permitted for IPPS hospitals.

Response: We disagree with the commenters' suggestion that we establish a cap for CBSAs with high wage index values. We believe the LTCH PPS wage index accurately reflects the relative labor costs in areas with both high wage index and low wage index values. In reference to the comment on LTCHs having an option to reclassify to a different CBSA, we did not propose this specific policy suggested by the commenters, but we will take this comment into consideration to potentially inform future rulemaking.

After consideration of the public comments we received, we are finalizing as proposed, that, beginning in FY 2023, we will apply a permanent 5-percent cap on any decrease to an LTCH's wage index from its wage index in the prior year. Also, after consideration of the public comments we received, we are establishing that this wage index cap policy will be implemented in a budget neutral manner by including the application of this policy in the area wage level budget neutrality factor that is applied to the standard Federal payment rate. We believe that this policy appropriately mitigates instability and significant negative impacts to LTCHs resulting from significant changes to the wage index and increases predictability of LTCH payments. We note that this provision is similar to our provision establishing a permanent 5-percent cap on annual wage index decreases for IPPS hospitals, as discussed in section III.N. of the preamble to this final rule.

We received no comments about our proposal to modify text at § 412.525(c)(1) to reflect the permanent cap on wage index decreases. Therefore, as we proposed, we are reflecting the permanent cap on wage index decreases at § 412.525(c)(1) by adding paragraphs (c)(1)(i) and (ii) to specify that CMS updates the wage index for LTCHs annually and that, beginning in FY 2023, if CMS determines that an LTCH's wage index value for a fiscal year would decrease by more than 5 percent as compared to the LTCH's wage index value for the prior year, we will limit the decrease to 5 percent for the fiscal year.

For each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped wage index. This includes the LTCH's final prior year wage index value, the LTCH's uncapped current year wage index value, and the LTCH's capped current year wage index value. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact their MAC to ensure that its wage index value is not less than 95 percent of the value paid to it for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

b. Permanent Cap on IPPS Comparable Wage Index Decreases

Determining LTCH PPS payments for short-stay-outlier cases (reflected in § 412.529) and site neutral payment rate cases (reflected in § 412.522(c)) requires calculating an ''IPPS comparable amount.'' For information on this ''IPPS comparable amount'' calculation, we refer the reader to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49608 through 49610). Determining LTCH PPS payments for LTCHs that do not meet the applicable discharge payment percentage (reflected in § 412.522(d)) requires calculating an ''IPPS equivalent amount.'' For information on this ''IPPS equivalent amount'' calculation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439 through 42445).

Calculating both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' requires adjusting the IPPS operating and capital standardized amounts by the applicable IPPS wage index for nonreclassified IPPS hospitals. That is, the standardized amounts are adjusted by the IPPS wage index for nonreclassified IPPS hospitals located in the same geographic area as the LTCH. Consistent with our proposal to apply a 5-percent cap on decreases in the LTCH PPS wage index and under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28685 through 28686), we also proposed, beginning with FY 2023 to apply a permanent 5-percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year. As with our proposed policy to apply a cap on decreases in the LTCH PPS wage index each year, we stated our belief that a permanent cap on applicable IPPS comparable wage index decreases would provide greater predictability to LTCHs by mitigating instability and significant negative impacts to LTCHs resulting from significant changes to the wage index and increase predictability of LTCH payments. Historically, we have not budget neutralized changes to LTCH PPS payments that result from the annual update of the IPPS wage index for nonreclassified IPPS hospitals. Consistent with this approach, we proposed that the cap on decreases in an LTCH's applicable IPPS comparable wage index not be applied in a budget neutral manner.

We proposed that an LTCH's applicable IPPS comparable wage index cap adjustment would be determined based on the wage index value assigned to the LTCH on the last day of the prior Federal fiscal year. We also proposed that new LTCHs that became operational during the prior Federal fiscal year be subject to the applicable IPPS comparable wage index cap. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year to which this final rule applies, we proposed that these LTCHs would not be subject to the applicable IPPS comparable wage index cap since they were not paid under the LTCH PPS in the prior year.

We received no comments on our proposal to apply a permanent 5-percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year. Therefore, we are finalizing this proposal without modification.

We received no comments about our proposal to modify text at § 412.529(d)(4)(ii)(B) and § 412.529(d)(4)(iii)(B) to reflect the permanent cap on IPPS comparable wage index decreases. Similarly, we received no comments on our proposal to remove the reference in § 412.529(d)(4)(iii)(B) related to the applicable large urban location adjustment. Therefore, as proposed, we are reflecting the permanent cap on IPPS comparable wage index decreases at § 412.529(d)(4)(ii)(B) to state that, beginning in FY 2023, an LTCH's applicable IPPS wage index used to adjust the IPPS operating standardized amount is subject to a 5-percent cap on decreases to an LTCH's applicable IPPS wage index value from the prior fiscal year. We also are reflecting the permanent cap on IPPS comparable wage index decreases at § 412.529(d)(4)(iii)(B) to state that, beginning in FY 2023, an LTCH's applicable IPPS wage index used to adjust the IPPS capital Federal rate is subject to a 5-percent cap on decreases to an LTCH's

applicable IPPS wage index value from the prior fiscal year. In addition, we are finalizing our proposal to remove the reference in § 412.529(d)(4)(iii)(B) related to the applicable large urban location adjustment because this policy is no longer applicable under the IPPS effective with discharges occurring on or after October 1, 2007 (72 FR 47400).

Similar to the information we made available for the cap on the LTCH PPS wage index values (described previously), for each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped applicable IPPS comparable wage index. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact its MAC to ensure that its applicable IPPS comparable wage index value is not less than 95 percent of the value paid to them for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

6. Budget Neutrality Adjustments for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2023, in accordance with § 412.523(d)(4), as we proposed, we applied an area wage level budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). As discussed in section V.B.5. of the Addendum to this final rule, for each year, beginning with FY 2023, we are limiting a hospital's LTCH PPS wage index value for the coming year by capping it at 95 percent of its prior year value. As also discussed previously, we are applying the 5-percent cap on wage index decreases, consistent with § 412.525(c)(2), in a budget neutral manner.

Specifically, as we proposed, we determined an area wage level adjustment budget neutrality factor that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2023 using the following methodology, which will incorporate our 5-percent cap on decreases in a hospital's wage index:

Step 1—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2022 wage index values and the FY 2022 labor-related share of 67.9 percent.

Step 2—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2023 wage index values (including application of the 5-percent cap on wage index decreases) and the FY 2023 labor-related share of 68.0 percent. (As noted previously, the changes to the wage index values based on updated hospital wage data are discussed in section V.B.4. of this Addendum to this final rule and the labor-related share is discussed in section V.B.3. of this Addendum to this final rule.)

Step 3—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2022 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the FY 2023 updates to the area wage level adjustment (calculated in Step 2) to determine the budget neutrality factor for updates to the area wage level adjustment for FY 2023 LTCH PPS standard Federal payment rate payments.

Step 4—Apply the FY 2023 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2023 LTCH PPS standard Federal payment rate after the application of the FY 2023 annual update.

In section I.F. of the preamble to this final rule, we discuss our use of FY 2021 claims data for the FY 2023 LTCH PPS ratesetting. We also state our belief that it is reasonable to assume that there will be fewer COVID–19 hospitalizations among Medicare beneficiaries at LTCHs in FY 2023 than there were in FY 2021. For this reason, we are making modifications in our determination of the FY 2023 MS–LTC–DRG relative weights and outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. We believe that these modifications will account for an anticipated decline in, but not elimination of, COVID–19 hospitalizations at LTCHs in FY 2023. However, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28687), when modeling payments for determining the area wage level adjustment budget neutrality factor, we proposed to use the full set of LTCH PPS standard Federal payment rate cases (including all COVID–19 cases) identified in the FY 2021 claims data. We stated that in the absence of a set of MedPAR claims that reflect our expectation that there will be fewer (but not zero) COVID–19 cases in FY 2023 as compared to the COVID–19 cases in the FY 2021 claims data, we believe this is the best data available for determining the budget neutrality factors. We also solicited feedback from commenters on alternative ways to use the FY 2021 claims data for purposes of calculating the FY 2023 budget neutrality factors. We received no comments on this proposal or our request for feedback on alternatives and are finalizing this proposal without modification. Therefore, for this final rule, when modeling payments for determining the budget neutrality factors, we used the full set of standard Federal payment rate cases (including all COVID–19 cases) identified in the FY 2021 claims data. We note this is consistent with the calculation of the budget neutrality factors for changes to the MS–LTC–DRG classifications and relative weights (including the 10-percent cap) discussed in section VIII.B.4.b. (Step 11) of the preamble of this final rule. We also note this is consistent with the approach under the IPPS as discussed in section II.A.4. of the Addendum of this final rule.

We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the FY 2023 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor. For this final rule, using the steps in the methodology previously described, we determined a FY 2023 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0004304. Accordingly, in section V.A. of the Addendum to this final rule, we applied the area wage level adjustment budget neutrality factor of 1.0004304 to determine the FY 2023 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

C. Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described. The methodology used to determine the COLA factors for Alaska and Hawaii is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our

current policy, we update the COLA factors using the methodology as previously described every 4 years (at the same time as the update to the labor-related share of the IPPS market basket) and we last updated the COLA factors for Alaska and Hawaii published by OPM for 2009 in FY 2022 (86 FR 45559 through 45560).

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Therefore, in this final rule, for FY 2023, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, as we proposed, we are continuing to use the COLA factors based on the 2009 OPM COLA factors updated through 2020 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2022 IPPS/LTCH PPS final rule. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii and for a discussion on the FY 2022 COLA factors, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45559 through 45560).)

COST-OF-LIVING ADJUSTMENT FACTORS (COLA): ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2023

Area	FY 2023
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Adjustment for LTCH PPS High Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

To maintain budget neutrality, consistent with the budget neutrality requirement at § 412.523(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 4-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and also are used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding CCRs and HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs in excess of the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should

not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

Consistent with our historical practice, as we proposed, we used the best available data to determine the LTCH total CCR ceiling for FY 2023 in this final rule. Specifically, in this final rule, we used our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the March 2022 update of the Provider Specific File (PSF), which is the most recent data available. Accordingly, we are establishing an LTCH total CCR ceiling of 1.312 under the LTCH PPS for FY 2023 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48117 through 48119).)

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals as described previously, without modification.

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this final rule, we are using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the March 2022 update of the PSF. As we proposed, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2022, through September 30, 2023, in Table 8C listed in section VI. of the Addendum to this final rule (and available via the internet on the CMS website). Consistent with our historical practice, as we also proposed, we used the best available data to determine the LTCH PPS statewide average total CCRs for FY 2023 in the final rule.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there were no short-term, acute care IPPS hospitals classified as rural or LTCHs located in these rural areas as of March 2022. Therefore, consistent with our existing methodology, we used the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C. While Massachusetts also has rural areas, the statewide average CCR for rural areas in Massachusetts is based on one IPPS provider whose CCR is an atypical 1.205. Because this is much higher than the statewide urban average (0.484) and furthermore implies costs greater than charges, as with Connecticut, we used the national average total CCR for rural IPPS hospitals for rural Massachusetts in Table 8C. Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, as we proposed, we are continuing to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are using this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals as described previously, without modification.

d. Reconciliation of HCO Payments

Under the HCO policy at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation (regardless of whether payment is based on the LTCH standard Federal payment rate or the site neutral payment rate). Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010), and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2023

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments (that is, the target percentage) under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been an LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562 through 45566), we finalized a number of technical changes to the methodology for determining the charge inflation factor and the CCR used when calculating the fixed-loss amount, while maintaining estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases. First, we

finalized a technical change to the methodology for determining the charge inflation factor applied to the charges on the MedPAR claims when calculating the fixed-loss amount for each FY. Second, we finalized a technical change to the methodology for determining the CCRs used when calculating the fixed-loss amount for each FY. These methodologies are described in greater detail later in this section of this Addendum.

(1) Charge Inflation Factor for Use in Determining the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2023

Under the LTCH PPS, the cost of each claim is estimated by multiplying the charges on the claim by the provider's CCR. Due to the lag time in the availability of claims data, when estimating costs for the upcoming payment year we typically inflate the charges from the claims data by a uniform factor.

For greater accuracy in calculating the fixed-loss amount, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562 through 45566), we finalized a technical change to our methodology for determining the charge inflation factor. Similar to the method used under the IPPS hospital payment methodology (as discussed in section II.A.4.h.(2) of the Addendum to this final rule), our methodology determines the LTCH charge inflation factor based on the historical growth in charges for LTCH PPS standard Federal payment rate cases, calculated using historical MedPAR claims data. In this section of this Addendum, we describe our charge inflation factor methodology using the most recently available data. However, as discussed in further detail later in this section, we did not propose to use the charge inflation factor derived from the most recently available data. Rather, we proposed using the charge inflation factor used in the FY 2022 IPPS/LTCH PPS final rule that was based on the growth in charges that occurred between FY 2018 and FY 2019.

Step 1—Identify LTCH PPS Standard Federal Payment Rate Cases

The first step in our methodology is to identify LTCH PPS standard Federal payment rate cases from the MedPAR claim files for the two most recently available Federal fiscal year time periods. For both fiscal years, consistent with our historical methodology for determining payment rates for the LTCH PPS, we remove any claims submitted by LTCHs that were all-inclusive rate providers as well as any Medicare Advantage claims. For both fiscal years, we also remove claims from providers that only had claims in one of the fiscal years.

Step 2—Remove Statistical Outliers

The next step in our methodology is to remove all claims from providers whose growth in average charges was a statistical outlier. We remove these statistical outliers prior to calculating the charge inflation factor because we believe they may represent aberrations in the data that would distort the measure of average charge growth. To perform this statistical trim, we first calculate each provider's average charge in both fiscal years. Then, we calculate a charge growth factor for each provider by dividing its average charge in the most recent fiscal year by its average charge in the prior fiscal year. Then we remove all claims for providers whose calculated charge growth factor was outside 3 standard deviations from the mean provider charge growth factor.

Step 3—Calculate the Charge Inflation Factor

The final step in our methodology is to use the remaining claims to calculate a national charge inflation factor. We first calculate the average charge for those remaining claims in both fiscal years. Then we calculate the national charge inflation factor by dividing the average charge in the more recent fiscal year by the average charge in the prior fiscal year.

Following the methodology described previously, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28690 through 28691), we computed a charge inflation factor based on the most recently available data. Specifically, we used the December 2021 update of the FY 2021 MedPAR file and the December 2020 update of the FY 2020 MedPAR as the basis of the LTCH PPS standard Federal payment rate cases for the two most recently available Federal fiscal year time periods, as described previously in our methodology. Therefore, we trimmed the December 2021 update of the FY 2021 MedPAR file and the December 2020 update of the FY 2020 MedPAR file as described in steps 1 and 2 of our methodology. To compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $239,245 ($14,013,531,722/58,574 cases) from FY 2020 to the average covered charge per case of $266,358 ($13,426,298,925/50,407 cases) from FY 2021. This rate-of-change was 11.3327 percent, which results in a 1-year charge inflation factor of 1.113327, and a 2-year charge inflation factor of 1.239497 (calculated by squaring the 1-year factor).

In the proposed rule, we recognized that this LTCH charge inflation factor calculated using the established methodology was abnormally high compared to recent historical levels prior to the COVID–19 PHE. We stated our belief that this abnormally high charge inflation factor is partially due to the high number of COVID–19 cases that were treated in LTCHs in FY 2021. We also stated our belief that there will be fewer COVID–19 cases in FY 2023 than in FY 2021 and therefore do not believe it is reasonable to assume charges will continue to increase at this abnormally high rate. Consequently, when determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023, we did not propose to use this charge inflation factor, which was based on the growth in charges that occurred between FY 2020 and FY 2021. Rather, we proposed to use the charge inflation factor determined in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45565), which was based on the growth in charges that occurred between FY 2018 and FY 2019 (the last 1-year period prior to the COVID–19 PHE).

The rate of LTCH charge growth determined in the FY 2022 IPPS/LTCH PPS final rule, based on the growth in charges that occurred between FY 2018 and FY 2019, was 6.0723 percent. This results in a 1-year charge inflation factor of 1.060723, and a 2-year charge inflation factor of 1.125133 (calculated by squaring the 1-year factor). Therefore, we proposed to inflate the billed charges obtained from the FY 2021 MedPAR file by this 2-year charge inflation factor of 1.125133 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023.

Comment: Nearly all commenters were appreciative of CMS's efforts to account for some of the pandemic-related factors in calculating the fixed-loss amount by applying the final FY 2022 charge inflation factor rather than the calculated amounts using our previously established methodology.

Response: We appreciate the support for this modification to our methodology in determining the charge inflation factor. We are finalizing our proposal to use the 2-year charge inflation factor of 1.125133 determined in the FY 2022 IPPS/LTCH PPS final rule, which was based on the growth in charges that occurred between FY 2018 and FY 2019 (the last 1-year period prior to the COVID–19 PHE) in calculating the fixed-loss amount. We note that using our ordinary data for this final rule, we calculated a 2-year charge inflation of 1.241308.

(2) CCRs for Use in Determining the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2023

For greater accuracy in calculating the fixed-loss amount, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562 through 45566), we finalized a technical change to our methodology for determining the CCRs used to calculate the fixed-loss amount. Similar to the methodology used for IPPS hospitals (as discussed in section II.A.4.h.(2). of the Addendum to this final rule), our methodology adjusts CCRs obtained from the best available PSF data by an adjustment factor that is calculated based on historical changes in the average case-weighted CCR for LTCHs. We believe these adjusted CCRs more accurately reflect CCR levels in the upcoming payment year because they account for historical changes in the relationship between costs and charges for LTCHs. In this section of this Addendum, we describe our CCR adjustment factor methodology using the most recently available data. However, as discussed in further detail later in this section of this Addendum, we did not propose to use the CCR adjustment factor derived from the most recently available data. Rather, we proposed using the CCR adjustment factor that was derived in the FY 2022 IPPS/LTCH PPS final rule, which is based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF.

Step 1—Assign Providers Their Historical CCRs

The first step in our methodology is to identify providers with LTCH PPS standard Federal payment rate cases in the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims). For each of these providers, we then identify the CCR from the most recently available PSF. For each of these providers we also identify the CCR from the PSF that was made available

one year prior to the most recently available PSF.

Step 2—Trim Providers With Insufficient CCR Data

The next step in our methodology is to remove from the CCR adjustment factor calculation any providers for which we cannot accurately measure changes to their CCR using the PSF data. We first remove any provider whose CCR was missing in the most recent PSF or prior year PSF. We next remove any provider assigned the statewide average CCR for their State in either the most recent PSF or prior year PSF. We lastly remove any provider whose CCR was not updated between the most recent PSF and prior year PSF (determined by comparing the effective date of the records).

Step 3—Remove Statistical Outliers

The next step in our methodology is to remove providers whose change in their CCR is a statistical outlier. To perform this statistical trim, for those providers remaining after application of Step 2, we calculate a provider-level CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year's PSF. We then remove any provider whose CCR growth factor was outside 3 standard deviations from the mean provider CCR growth factor. These statistical outliers are removed prior to calculating the CCR adjustment factor because we believe that they may represent aberrations in the data that would distort the measure of average annual CCR change.

Step 4—Calculate a CCR Adjustment Factor

The final step in our methodology is to calculate, across all remaining providers after application of Step 3, an average case-weighted CCR from both the most recent PSF and prior year PSF. The provider case counts that we use to calculate the case-weighted average are determined from claims for LTCH standard Federal rate cases from the most recent MedPAR claims file. We note when determining these case counts, consistent with our historical methodology for determining the MS–LTC–DRG relative weights, we do not count short-stay outlier claims as full cases but instead as a fraction of a case based on the ratio of covered days to the geometric mean length of stay for the MS–LTC–DRG grouped to the case. We calculate the national CCR adjustment factor by dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

Following the methodology described previously, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28691 through 28692) we computed a CCR adjustment factor based on the most recently available data. Specifically, we used the December 2021 PSF as the most recently available PSF and the December 2020 PSF as the PSF that was made available one year prior to the most recently available PSF, as described in our methodology. In addition, we used claims from the December 2021 update of the FY 2021 MedPAR file in our calculation of average case-weighted CCRs described in Step 4 of our methodology. Specifically, following the methodology described previously and, for providers with LTCH PPS standard Federal payment rate cases in the December 2021 update of the FY 2021 MedPAR file, we identified their CCRs from both the December 2020 PSF and December 2021 PSF. After performing the trims outlined in our methodology, we used the LTCH PPS standard Federal payment rate case counts from the FY 2021 MedPAR file (classified using proposed Version 40 of the GROUPER) to calculate case-weighted average CCRs. Based on this data, we calculated a December 2020 national average case-weighted CCR of 0.244856 and a December 2021 national average case-weighted CCR of 0.234409. We then calculated a national CCR adjustment factor by dividing the December 2021 national average case-weighted CCR by the December 2020 national average case-weighted CCR. This results in a 1-year national CCR adjustment factor of 0.957334.

Unlike the charge inflation factor calculated using the most recently available data, the CCR adjustment factor calculated previously is not significantly different from historical levels. However, consistent with our proposal to derive our proposed charge inflation factor for FY 2023 based on data from the last 1-year period prior to the COVID–19 PHE, we proposed using the CCR adjustment factor determined in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45565), which was based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF (the last 1-year period prior to the COVID–19 PHE). We note that the CCR adjustment factor of 0.961554 determined in the FY 2022 IPPS/LTCH PPS final rule is close to the CCR adjustment factor we calculated previously using the most recently available data.

Comment: Nearly all commenters were appreciative of CMS's efforts to account for some of the pandemic-related factors in calculating the fixed-loss amount by applying the final FY 2022 CCR adjustment factor rather than the calculated amounts using our previously established methodology.

Response: We appreciate the support for our modified methodology for determining the CCR adjustment factor. We are finalizing our proposal to use the CCR adjustment factor of 0.961554 determined in the FY 2022 IPPS/LTCH PPS final rule, which was based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF (the last 1-year period prior to the COVID–19 PHE) in calculating the fixed loss amount. When calculating the fixed-loss amount for FY 2023, consistent with our proposal, we assigned the statewide average CCR for the upcoming fiscal year to all providers who were assigned the statewide average in the March 2022 PSF or whose CCR was missing in the March 2022 PSF. For all other providers, we multiplied their CCR from the March 2022 PSF by the 1-year national CCR adjustment factor of 0.961554. We note that using our ordinary data for this final rule, we calculated a 1-year national CCR adjustment factor of 0.959468.

(3) Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2023

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28123 through 28125), we discussed our proposed use of FY 2021 claims data for the FY 2023 LTCH PPS ratesetting. In the proposed rule, we stated our belief that it is reasonable to assume that there will be fewer COVID–19 hospitalizations among Medicare beneficiaries at LTCHs in FY 2023 than there were in FY 2021. For this reason, as discussed previously, we proposed modifications to the charge inflation and CCR adjustment factors used in determining the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases.

However, when modeling payments for the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases, we proposed to use the full set of LTCH PPS standard Federal payment rate cases (including all COVID–19 cases) identified in the FY 2021 claims data. In the absence of a set of MedPAR claims that reflect our expectation that there will be fewer (but not zero) COVID–19 cases in FY 2023 as compared to the COVID–19 cases in the FY 2021 claims data, we stated our belief that this is the best data available for determining the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. In the proposed rule, we solicited feedback from commenters on alternative ways to use the FY 2021 claims data for purposes of calculating the FY 2023 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases.

In the proposed rule, for FY 2023, using the best available data, we calculated a fixed-loss amount that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in the final rule). Therefore, based on LTCH claims data from the December 2021 update of the FY 2021 MedPAR file adjusted for charge inflation and adjusted CCRs from the December 2021 update of the PSF, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we proposed a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023 of $44,182 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2023 payments for such cases. We also proposed to continue making an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $44,182). Consistent with our historical practice, we proposed to use the best available LTCH claims data and CCR data, if applicable, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28740 through 28741), we also considered as an alternative, to use the FY 2021 data without any of our methodological changes that account for an anticipated decline in COVID–19 cases in FY 2023. We noted in the proposed rule that,

under this alternative, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be $61,842

Comment: We received numerous comments objecting to our proposed fixed-loss amount of $44,182 for standard Federal payment rate cases. Commenters stated that the increase over last year's fixed-loss amount of $33,015, particularly on top of the increase to the FY 2021 threshold of $27,195, would have a significant financial impact on LTCHs. Moreover, commenters stated their belief that the proposed fixed-loss amount would result in underpayments to LTCHs treating high-cost patients, hindering the ability of LTCHs to provide care to the sickest beneficiaries. Some commenters stated that CMS should lower the outlier fixed-loss amount in response to rising costs that have and will continue to impact LTCHs.

Several commenters expressed concern about our proposed use of FY 2021 claims data in determining the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. Commenters recommended several alternative data sources or methodologies for calculating the outlier fixed-loss amount that they believed would more accurately reflect the impact of the COVID–19 pandemic on utilization in FY 2023.

The most commonly recommended approach by commenters was to determine the outlier fixed-loss amount as an average of the outlier fixed-loss amounts calculated using both FY 2019 and FY 2021 claims data, thereby incorporating data from one year before the COVID–19 PHE and one year during the COVID–19 PHE. Some commenters believed that this approach would better account for the uncertainty on whether the abnormal levels of charges and costs reflected in the FY 2021 claims data caused by the COVID–19 pandemic will normalize in FY 2023. Another commenter, while suggesting this alternative methodology, expressed its belief that costs in FY 2023 will more closely resemble pre-pandemic costs than what was experienced in FY 2021. Some commenters stated that this approach would be consistent with other FY 2023 proposals aimed to institute stability and predictability in payments from year to year.

Some commenters suggested that CMS use its regulatory authority under the PHE to establish the FY 2023 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases at the FY 2022 level. Other commenters, while expressing concerns that the FY 2021 claims were atypical, requested CMS to reexamine its methodology and better account for data anomalies.

In its comment letter, MedPAC presented an alternative approach for CMS to consider in which the FY 2023 fixed-loss amount would be established by averaging the outlier fixed-loss amounts calculated with and without COVID–19 cases in the FY 2021 data. MedPAC believes that this approach would be consistent with the approach CMS proposed for calculating the MS–LTC–DRG relative weights and would reflect the assumption that there will be fewer COVID–19 cases in FY 2023 as compared to FY 2021.

Commenters strongly objected to the alternative fixed loss amount we considered in section I.O. of Appendix A of the proposed rule which was calculated using FY 2021 data without any of the methodological changes to account for anticipated declines in COVID–19 cases in FY 2023.

Response: We thank commenters for their feedback. In response to commenters' concerns, we considered recommendations made by commenters on how we could better account for the impact of the COVID–19 PHE on the data used for determining the outlier fixed-loss amount.

We do not agree with commenters who recommend that CMS use it regulatory authority under the PHE to establish an alternative outlier fixed-loss amount or commenters who suggested that CMS lower the outlier-fixed loss amount in response to rising costs at LTCHs. We note that in accordance with § 412.525(a)(2)(ii), which implements section 1886(m)(7)(B) of the Act, CMS must determine a fixed-loss amount for LTCH PPS standard Federal payment rate cases that we project will result in total outlier payments for FY 2023 being equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We do not believe that CMS has the statutory authority to establish an outlier fixed-loss amount that does not meet this requirement.

With respect to the commenters who suggested we determine the outlier fixed-loss amount based on an average of the fixed-loss amounts calculated using FY 2019 and FY 2021 data, we continue to recognize that there is uncertainty regarding the utilization and costs that LTCHs will experience in FY 2023. However, based on the information available at this time on the trajectory of the COVID–19 PHE, consistent with the discussion in section I.F. of the preamble to this final rule, we do not believe averaging the fixed-loss amounts calculated using FY 2019 and FY 2021 data is the best approach for determining an outlier fixed-loss amount that will reflect a reasonable estimation of the mix and relative resource use of cases that will be treated at LTCHs in FY 2023. Rather, we believe averaging the outlier-fixed loss thresholds calculated using FY 2021 data including and excluding COVID–19 claims, as suggested by MedPAC, better reflects our belief that it is reasonable to assume there will be fewer COVID–19 hospitalizations among Medicare beneficiaries in LTCHs in FY 2023 than there were in FY 2021 (as discussed in section I.F of the preamble to this final rule). In addition, we agree this approach would be most consistent with the approach we proposed and are finalizing for calculating the MS–LTC–DRG relative weights, as discussed in section VIII.B.3.a. of the preamble to this final rule. As discussed later in this section, we are adopting the approach suggested by MedPAC when determining the FY 2023 outlier fixed loss amount.

With respect to commenters' concerns about data anomalies contributing to a higher outlier fixed-loss amount, we note we recently became aware of an anomaly in the data that contributed to the increase in the proposed outlier fixed-loss amount. Under our existing outlier policy, in general, the CCR from an LTCH's latest settled or tentatively settled cost report is used in determining its outlier payments. In the case of one LTCH, in particular, we observed that its rate-of-charge increases greatly exceed their rate-of-cost increases. In other words, the charges reported on its claims were increasing at a significantly faster pace than their reported costs. Because there is a time lag between the CCR from the latest settled or tentatively settled cost report and current charges, this sizable differential in the rate-of-increases for charges and costs results in CCRs that are too high relative to the actual relationship between the LTCH's charges and costs at the time of the discharge. This in turn results in an overestimation of the LTCH's current costs per case at the time of the discharge, and high amounts of HCO payments. In FY 2021, this LTCH's charges per case increased to extreme levels. In the FY 2021 MedPAR file, we identified over 50 LTCH PPS standard Federal payment rate cases for this LTCH with charges that exceed $9 million. In addition, this LTCH received outlier payments for over 80 percent of its LTCH PPS standard Federal payment rate cases identified in the FY 2021 MedPAR file. As discussed previously, under the HCO policy at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation (regardless of whether payment is based on the LTCH standard Federal payment rate or the site neutral payment rate). Specifically, any such payments are reconciled at cost report settlement based on the CCR that was calculated for the cost reporting period coinciding with the discharge. Based on information from the provider, we believe that these extreme levels of charges will not persist into FY 2023. For this reason, we do not believe it would be appropriate to include cases for this LTCH (CCN 312024) in our model for determining the FY 2023 outlier fixed-loss amount. Therefore, as discussed later in this section, we are excluding them from our calculations of the FY 2023 outlier fixed-loss amount.

After consideration of all comments received, we are modifying our proposed approach for determining the FY 2023 outlier fixed-loss amount. As discussed, we are adopting the suggested approach to establish the FY 2023 outlier fixed-loss amount based on the average of the outlier-fixed loss thresholds calculated using FY 2021 data including and excluding COVID–19 claims. As discussed, we are also excluding claims from CCN 312024 from the FY 2021 claims data used in determining the FY 2023 outlier fixed-loss amount. As discussed previously, we also are finalizing our proposal to use the charge inflation and CCR adjustment factors determined in the FY 2022 IPPS/LTCH PPS final rule when calculating the FY 2023 outlier fixed-loss amount.

For this final rule, for FY 2023, using the best available data, we calculated a fixed-loss amount that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in this final rule). Based on the full set of LTCH claims

data (including COVID–19 cases) from the March 2022 update of the FY 2021 MedPAR file adjusted for charge inflation and using adjusted CCRs from the March 2022 update of the PSF, we calculated a fixed-loss amount of $37,900. Based on the set of LTCH claims data that excludes COVID–19 cases from the March 2022 update of the FY 2021 MedPAR file adjusted for charge inflation and using adjusted CCRs from the March 2022 update of the PSF, we calculated a fixed-loss amount of $39,135. We identified COVID–19 cases as any claim in the FY 2021 MedPAR file with a principal or secondary diagnosis of COVID–19 (ICD–10–CM diagnosis code U07.1), just as we did for the calculation of the FY 2023 MS–LTC–DRG relative weights. Accordingly, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are establishing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023 of $38,518, which is the average of the fixed-loss amounts calculated from FY 2021 claims data including and excluding COVID–19 cases. We project that this fixed-loss amount will result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2023 payments for such cases. We are continuing, as proposed, to make additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $38,518). We note that this revised amount is considerably lower than our proposed fixed-loss amount of $44,182. We also note that if we had not excluded CCN 312024 from our calculations, the averaged fixed-loss amount would have been $39,556.

4. High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FYs 2019 through 2022, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases, FY 2018 and FY 2019 claims for these cases were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2022, our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic.

In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2022 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2022. In particular, in FY 2022, we established the fixed-loss amount for site neutral payment rate cases as the FY 2021 IPPS fixed-loss amount of $30,988 (86 FR 45567).

As discussed in section I.F. of the preamble of this final rule, we are finalizing our proposal to use FY 2021 data in the FY 2023 LTCH PPS ratesetting. Section 3711(b)(2) of the CARES Act, which provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period, was in effect for the entirety of FY 2021. Therefore, all LTCH PPS cases in FY 2021 were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. Because not all FY 2021 claims in the data used for this final rule were subject to the site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2022 when developing a fixed-loss amount for site neutral payment rate cases for FY 2023. Our actuaries continue to project that the costs and resource use for FY 2023 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. (Based on the FY 2021 LTCH claims data used in the development of this final rule, if the provisions of the CARES Act had not been in effect, approximately 72 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 28 percent of LTCH cases would have been paid the site neutral payment rate for discharges occurring in FY 2021.)

For these reasons, we proposed that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2023 is the IPPS fixed-loss amount for FY 2023. Therefore, consistent with past practice, we proposed that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we proposed a fixed-loss amount for site neutral payment rate cases of $43,214, which is the same proposed FY 2023 IPPS fixed-loss amount discussed in section II.A.4.j.(1). of the Addendum to the proposed rule. Accordingly, for FY 2023, we proposed to calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the fixed-loss amount for site neutral payment rate cases of $43,214).

Comment: Some commenters opposed the proposed fixed-loss amount for site neutral payment rate cases. A commenter stated that increases in the fixed-loss amount for site neutral payment rate cases should be limited to no more than the market basket percent increase. Other commenters stated that CMS should calculate the fixed-loss amount for site neutral payment rate cases using a combination of FY 2019 and FY 2021 data.

Response: As stated earlier, our actuaries continue to project that site neutral payment rate cases in FY 2023 will mirror an IPPS case paid under the same MS–DRG. That is, our actuaries continue to project that the costs and resource use for FY 2023 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS DRG, on average, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2023 is the IPPS fixed-loss amount for FY 2023. With respect to comments on the data used in determining the site neutral fixed-loss amount, we refer the reader to section II.A.4. of the addendum to this final rule for a complete summary and

response to comments received on our proposed use of FY 2021 data and our proposed modifications to our usual methodology when determining the FY 2023 outlier fixed-loss amounts for IPPS cases, which as described later in this section, is the same as the site neutral fixed-loss amount.

In this final rule, after considering public comments on our proposals, we are finalizing our proposals as described previously, without modification. Therefore, for FY 2023, as we proposed, we are establishing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed loss amount. That is, we are establishing a fixed-loss amount for site neutral payment rate cases of $38,859, which is the same FY 2023 IPPS fixed loss amount discussed in section II.A.4.j.(1). of the Addendum to this final rule. Accordingly, under this policy, for FY 2023, we will calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of site neutral payment rate payment and the fixed loss amount) for site neutral payment rate cases of $38,859.

In establishing a HCO policy for site neutral payment rate cases, we proposed a budget neutrality adjustment under § 412.522(c)(2)(i). We proposed this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2023 would not result in any increase in estimated aggregate FY 2023 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2023. Consistent with our historical practice, we proposed continuing this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the proposed fixed-loss threshold would result in FY 2023 HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2023 would not result in any increase in estimated aggregate FY 2023 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2023. To achieve this, for FY 2023, we proposed applying a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0 − 5.1/100 = 0.949) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We proposed that, consistent with our current policy, this HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

Comment: A commenter, in keeping with comments we have received since the inception of the dual rate payment system that created the site neutral payment rate, objected to the proposed site neutral payment rate HCO budget neutrality adjustment. The commenter's objection continues to be based on the belief that, because the IPPS base rates used in the IPPS comparable per diem amount calculation of the site neutral payment rate include a budget neutrality adjustment for IPPS HCO payments (for example, a 5.1 percent adjustment on the operating IPPS standardized amount), a ''second'' budget neutrality factor is unnecessary and duplicative.

Response: We continue to disagree with the commenters that a budget neutrality adjustment for site neutral payment rate HCO payments is unnecessary or duplicative. We have stated such disagreement during each previous rulemaking cycle. We refer readers to 84 FR 42648 through 42649, 83 FR 41737 through 41738, 82 FR 38545 through 38546, 81 FR 57308 through 57309, and 80 FR 49621 through 49622 for a more detailed discussion in response to such comments.

After consideration of public comments, for the reasons discussed previously, we are adopting our proposed site neutral payment rate HCO budget neutrality adjustment as final without modification. Specifically, for FY 2023, as we proposed, we are applying a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0 − 5.1/100 = 0.949) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this HCO budget neutrality adjustment will not apply to the HCO portion of the site neutral payment rate amount.

E. Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the site neutral payment rate at § 412.522. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2023, as discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28694) and in greater detail in section V.E.4.b. of the preamble of this final rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 65.71 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2023. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 49.28 percent (the product of 75 percent and 65.71 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2023, we

projected that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 74.28 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 49.28 percent = 74.28 percent).

Therefore, for FY 2023, in the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 74.28 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we proposed that if more recent data became available, we would use that data to determine this factor in the final rule.

We did not receive any public comments in response to our proposal. In addition, there are no more recent data available to use that would affect the calculations determined in the proposed rule. Therefore, we are finalizing our proposal that, for FY 2023, the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 74.28 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act.

F. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2023

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the proposed FY 2023 values are shown in Tables 12A through 12B listed in section VI. of the Addendum to this final rule and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the final FY 2023 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this final rule, we are establishing an LTCH PPS standard Federal payment rate for FY 2023 of $46,432.77 as discussed in section V.A. of the Addendum to this final rule. We illustrate the methodology to adjust the LTCH PPS standard Federal payment rate for FY 2023, applying our finalized LTCH PPS amounts for the standard Federal payment rate, MS–LTC–DRG relative weights, and wage index in the following example:

Example:

During FY 2023, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a FY 2023 LTCH PPS wage index value of 1.0437 (as shown in Table 12A listed in section VI. of the Addendum to this final rule). The Medicare patient case is classified into proposed MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a relative weight for FY 2023 of 0.9606 (as shown in Table 11 listed in section VI. of the Addendum to this final rule). The LTCH submitted quality reporting data for FY 2023 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2023, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2023 LTCH PPS standard Federal payment rate ($46,432.77) by the labor-related share (0.680 percent) and the wage index value (1.0437). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (0.320 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which is then multiplied by the MS–LTC–DRG relative weight (0.9606) to calculate the total adjusted LTCH PPS standard Federal prospective payment for FY 2023 ($45,928.75). The table illustrates the components of the calculations in this example.

Unadjusted LTCH PPS Standard Federal Prospective Payment Rate	$46,432.77
Labor-Related Share	x 0.68
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $31,574.28
Wage Index (CBSA 16984)	x 1.0437
Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $32,954.08
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($46,432.77 x 0.32)	+ $14,858.49
Adjusted LTCH PPS Standard Federal Payment Amount	= $47,812.57
MS-LTC-DRG 189 Relative Weight	x 0.9606
Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $45,928.75

VI. Tables Referenced in This Final Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this final rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2022, for the FY 2023 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available through the internet. Specifically, all IPPS tables listed in the final rule, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available through the internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules. For additional discussion of the information included in the IPPS and LTCH PPS tables associated with the IPPS/LTCH PPS proposed and final rules, as well as prior changes to the information included in these tables, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45569 through 45571).

In addition, under the HAC Reduction Program, established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. The hospital-level data for the FY 2023 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28695), we noted that Tables 7A and 7B historically contained the Medicare prospective payment system selected percentile lengths of stay for the MS–DRGs for the prior year and upcoming fiscal year. As discussed in section II.E of the FY 2023 IPPS/LTCH proposed rule (87 FR 28197—28204), we proposed to determine the MS–DRG relative weights for FY 2023 by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data. Because we proposed to use MS–DRG weights based on an average of the relative weights, we stated that the percentile lengths of stay, which are based on separate sets of MS–DRG relative weights prior to averaging are not applicable to the proposed averaged MS–DRG relative weights for FY 2023. The separate percentile lengths of stay statistics are only applicable to the relative weights as calculated with and without COVID–19 cases. Additionally, we also stated that unlike the other files listed as tables in this section of the final rule that typically

contain information/variables relating to a hospital's IPPS claim for payment, Tables 7A and 7B are informational files containing percentile lengths of stay that are not used for claim payment. Therefore, in the FY 2023 IPPS/LTCH proposed rule (87 FR 28695), beginning with the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to instead provide the percentile length of stay information previously included in Tables 7A and 7B in the supplemental AOR/BOR data file, as described in section XII.A. of this final rule, which contains additional data relevant to the MS–DRG relative weights. For FY 2023, because we proposed to average the relative weights, in the proposed rule we provided an AOR/BOR file for the relative weights calculated with COVID–19 cases in the December 2021 update of the FY 2021 MedPAR file and an AOR/BOR file for the relative weights calculated without COVID–19 cases in the December 2021 update of the FY 2021 MedPAR file (we note, for this final rule we used the March 2022 update of the FY 2021 MedPAR file). Therefore, instead of including the percentile lengths of stay that are typically in Tables 7A and 7B (that is, for the proposed rule, the selected percentile lengths of stay based on the MedPAR data and MS–DRGs for the prior year and upcoming fiscal year (for FY 2023, this would be the version 40 GROUPER and version 39 GROUPER)) we proposed to include this statistical information in the AOR/BOR File for the relative weights as calculated with and without COVID–19 cases. The AOR/BOR files can be found on the FY 2023 IPPS final rule home page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We note, as discussed in section II.E of this final rule, after consideration of the public comments, we are finalizing our proposal to determine the MS–DRG relative weights for FY 2023 by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data.

We did not receive any comments on our proposal previously noted. Therefore, we are finalizing as proposed without modification that beginning with the FY 2023 IPPS/LTCH PPS proposed and final rules, to provide the percentile length of stay information previously included in Tables 7A and 7B in the supplemental AOR/BOR data file.

For this FY 2023 IPPS/LTCH final rule, because we are finalizing to average the relative weights, similar to the proposed rule, we are providing an AOR/BOR file for the relative weights calculated with COVID–19 cases in the March 2022 update of the FY 2021 MedPAR file and an AOR/BOR file for the relative weights calculated without COVID–19 cases in the March 2022 update of the FY 2021 MedPAR file. Both of these files will include the percentile lengths of stay that were typically in Tables 7A and 7B.

As was the case for the FY 2022 IPPS/LTCH PPS proposed and final rules, we are no longer including Table 15, which had typically included the fiscal year readmissions payment adjustment factors because hospitals have not yet had the opportunity to review and correct the data before the data are made public under our policy regarding the reporting of hospital-specific data. After hospitals have been given an opportunity to review and correct their calculations for FY 2023, we will post Table 15 (which will be available via the internet on the CMS website) to display the final FY 2023 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2022. We expect Table 15 will be posted on the CMS website in the fall of 2022.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified in this final rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this final rule are generally available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled ''FY 2023 IPPS Final Rule Home Page'' or ''Acute Inpatient-Files-for Download.'' We refer readers to section I.O. of the Appendix A of this final rule for a discussion of the supplemental data files we are making available based on the use of the FY 2021 data without the modifications to our usual methodologies for the calculation of the FY 2023 MS–DRG and MS–LTC–DRG relative weights or our usual methodologies for the determination of the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases for this FY 2023 ratesetting, which we are also making available on the CMS website.

Table 2—Case-Mix Index and Wage Index Table by CCN—FY 2023 Final Rule

Table 3—Wage Index Table by CBSA—FY 2023 Final Rule

Table 4A—List of Counties Eligible for the Out-Migration Adjustment Under Section 1886(d)(13) of the Act—FY 2023 Final Rule

Table 4B—Counties Redesignated Under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2023 Final Rule

Table 5—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2023

Table 6A—New Diagnosis Codes—FY 2023

Table 6B—New Procedure Codes—FY 2023

Table 6C—Invalid Diagnosis Codes—FY 2023

Table 6D—Invalid Procedure Codes—FY 2023

Table 6E.—Revised Diagnosis Code Titles—FY 2023

Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2023

Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2023

Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2023

Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2023

Table 6I.—Complete MCC List—FY 2023

Table 6I.1.—Additions to the MCC List—FY 2023

Table 6I.2.—Deletions to the MCC List—FY 2023

Table 6J.—Complete CC List—FY 2023

Table 6J.1.—Additions to the CC List—FY 2023

Table 6J.2.—Deletions to the CC List—FY 2023

Table 6K.—Complete List of CC Exclusions—FY 2023

Table 6P.—ICD–10–CM and ICD–10–PCS Codes for MS–DRG Changes—FY 2023

(Table 6P contains multiple tables, 6P.1a. through 6P.1f that include the ICD–10–CM and ICD–10–PCS code lists relating to specific MS–DRG changes. These tables are referred to throughout section II.D. of the preamble of this final rule.)

Table 8A.—FY 2023 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—FY 2023 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 18.—FY 2023 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2023 final rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1771–F:

Table 8C.—FY 2023 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2022, through September 30, 2023

Table 12A.—LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2022, through September 30, 2023

Table 12B.—LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2022, through September 30, 2023

TABLE 1A.—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (67.6 PERCENT LABOR SHARE/32.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2023

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 3.8 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.725 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 2.775 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.3 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,310.00	$2,065.74	$4,182.32	$2,004.54	$4,267.44	$2,045.34	$4,139.76	$1,984.15

TABLE 1B.—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2023

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 3.8 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.725 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 2.775 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.3 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,952.96	$2,422.78	$3,835.85	$2,351.01	$3,913.92	$2,398.86	$3,796.82	$2,327.09

TABLE 1C.—ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2023

	Rates if Wage Index Greater Than 1		Hospital is a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 3.8)		Hospital is NOT a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 1.75)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$3,952.96	$2,422.78	$3,874.89	$2,374.93

[1] For FY 2023, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D.—CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2023

	Rate
National	$483.76

TABLE 1E.—LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2023

	Full Update (3.8 Percent)	Reduced Update* (1.8 Percent)
Standard Federal Rate	$46,432.77	$45,538.11

* For LTCHs that fail to submit quality reporting data for FY 2023 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary in order to make payment and policy changes under the IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also, as we note later in this Appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule, such as the updates to the IPPS and LTCH PPS rates, and the final policies and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

a. Update to the IPPS Payment Rates

In accordance with section 1886(b)(3)(B) of the Act and as described in section V.A. of the preamble to this final rule, we updated the national standardized amount for inpatient hospital operating costs by the applicable percentage increase of 3.8 percent (that is, a 4.1 percent market basket update with a reduction of 0.3 percentage point for the productivity adjustment) and by a 0.5 percentage point adjustment required under section 414 of the MACRA. We are also applying the applicable percentage increase (including the market basket update and the productivity adjustment) to the hospital-specific rates.

Hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 2.775 percent. Hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of 0.725 percent.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of −0.3 percent, which reflects a one-quarter percent reduction of the market basket update for failure to submit quality data and a three-quarter percent reduction of the market basket update for being identified as not a meaningful EHR user.

b. Use of FY 2021 Data in the FY 2023 IPPS and LTCH PPS Ratesetting

As discussed in section I.A. of the preamble of this final rule, we believe that it is reasonable to assume that some Medicare beneficiaries will continue to be hospitalized with COVID–19 at IPPS hospitals and LTCHs in FY 2023. Accordingly, we believe it is appropriate to use FY 2021 data, specifically the FY 2021 MedPAR claims file and the FY 2020 HCRIS dataset (which contains data from many cost reports ending in FY 2021 based on each hospital's cost reporting period) as the most recent available data during the period of the COVID–19 PHE, for purposes of the FY 2023 IPPS and LTCH PPS ratesetting. However, we also believe it is reasonable to assume based on the information available at this time that there will be fewer COVID 19 hospitalizations in FY 2023 than in FY 2021 given the more recent trends in the CDC hospitalization data since the Omicron variant peak in January, 2022. Accordingly, because we anticipate Medicare inpatient hospitalizations for COVID–19 will continue in FY 2023 but at a lower level, we are using FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting but with modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021.

First, we are modifying the calculation of the FY 2023 MS–DRG and MS LTC DRG relative weights. The final policy to modify the methodology for determining the FY 2023 IPPS MS–DRG relative weights is discussed in section II.E. of the preamble of this final rule. The final policy to modify the methodology for determining the FY 2023 LTCH PPS MS–LTC–DRG relative weights is discussed in greater detail in section VIII.B. of the preamble of this final rule. This modification primarily impacts MS–DRGs and MS–LTC DRGs with larger numbers of COVID–19 cases, for example MS–DRG 870 (Septicemia or Severe Sepsis with MV >96 hours). IPPS hospitals that disproportionately treat high numbers of COVID–19 cases will generally see increased non-outlier payments compared to what those payments would have been had we excluded the COVID–19 cases entirely, and lower payments compared to if we had not made any modifications to our usual methodology for calculating the relative weights. This final policy reflects our belief that there will be fewer COVID–19 cases in FY 2023 than in FY 2021, but there will still be COVID–19 cases in FY 2023.

Second, we also are modifying our methodologies for determining the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases. The final policy to modify the methodology for determining the FY 2023 outlier fixed-loss amounts for IPPS cases is discussed in section II.A.4. of the Addendum to this final rule. The final policy to modify the methodology for determining the FY 2023 outlier fixed loss amounts for LTCH PPS standard Federal payment rate cases is discussed in section V.D.3. of the Addendum to this final rule. This modification has a greater impact on hospitals with larger numbers of outlier cases. IPPS hospitals that receive outlier payments will see lower outlier payments compared to what those payments would have been had we excluded the COVID–19 cases entirely, and higher outlier payments compared to if we had not made any modifications to our usual methodology for calculating the outlier fixed loss amount. Again, this final policy reflects our belief that there will be fewer COVID–19 cases in FY 2023 than in FY 2021, but there will still be COVID–19 cases in FY 2023.

c. Cap on Reductions in Medicare Severity Diagnosis-Related Group (MS–DRG) Relative Weights

As described in section II.E.2. of the preamble of this final rule, we have further considered requests made by commenters that we address year-to-year fluctuations in relative weights, particularly for low volume MS–DRGs, and to mitigate the financial impacts of significant fluctuations. As described in section II.E.2. of this final rule, for these low volume MS–DRGs, fluctuations in the volume or mix of cases and/or the presence of a few high cost or low cost cases can have a disproportionate impact on the calculated relative weight, thus resulting in greater year-to-year variation in the relative weights for these MS–DRGs. Consistent with

our statutory authority under section 1886(d)(4)(B) and (C) of the Act to assign and update appropriate weighting factors, beginning in FY 2023, we are finalizing a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year. This final policy is consistent with our general authority to assign and update appropriate weighting factors as part of our annual reclassifications of the MS–DRGs and recalibration of the relative weights under sections 1886(d)(4)(B) and (C)(i) of the Act, as well as the requirements of section 1886(d)(4)(C)(iii) of the Act, which specifies that the annual DRG reclassification and recalibration of the relative weights be made in a manner that ensures that aggregate payments to hospitals are not affected. In addition, we have authority to implement this cap and the associated budget neutrality adjustment under our special exceptions and adjustments authority at section 1886(d)(5)(I)(i) of the Act, which similarly gives the Secretary broad authority to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. For the vast majority of hospitals, the impact of the 10-percent cap, inclusive of the budget neutrality factor, is less than 0.1 percent. We note that the impact of not finalizing a 10-percent cap for FY 2023, or finalizing a higher cap, such as 15 or 20 percent, would be most marked for hospitals whose case mix includes more MS–DRGs experiencing reductions of greater than 10-percent for FY 2023. The impact of finalizing a lower cap, such as 5 percent, would be increases to hospitals whose case mix includes more MS–DRGs experiencing reductions of between 5 and 10 percent, with a corresponding increase in the budget neutrality adjustment for all hospitals.

d. Add-On Payments for New Services and Technologies

Consistent with sections 1886(d)(5)(K) and (L) of the Act, CMS reviews applications for new technology add-on payments based on the eligibility criteria at 42 CFR 412.87. As set forth in 42 CFR 412.87(e)(1), CMS considers whether a technology meets the criteria for the new technology add-on payment and announces the results as part of its annual updates and changes to the IPPS.

(1) Proposal To Use National Drug Codes (NDCs) for Identification of Certain Therapeutic Agents Approved for New Technology Add-On Payment

In section II.F.8. of the preamble of this final rule, we detail our proposal to use National Drug Codes (NDCs) to identify cases involving use of therapeutic agents approved for new technology add-on payments, and discuss comments received. After consideration of the comments received, including concerns that our proposed use of NDCs for this purpose may impose new administrative burdens to hospitals, we are not finalizing this proposal, and will instead reassess this policy proposal in future rulemaking.

(2) Publicly Post Applications for New Technology Add-On Payments

As discussed in section II.F.9. of the preamble of this final rule, beginning with the FY 2024 application cycle for new technology add-on payments, we are finalizing our proposal to publicly post online the completed application forms and certain related materials, including updated application information submitted subsequent to the initial application submission, with the exception of cost and volume information and certain additional information and materials, as discussed more fully in section II.F.9. of the preamble of this final rule. We have received requests from the public to access and review the new technology add-on payment applications to further facilitate comment on whether a technology meets the new technology add-on payment criteria. Making this information publicly available may also foster greater input from interested parties based on their review of the completed application forms and related materials.

Additionally, we believe that posting the applications online will reduce the risk that we may inadvertently omit or misrepresent relevant information submitted by applicants, or are perceived as misrepresenting such information, in our summaries in the rules. It also will streamline our evaluation process, including the identification of critical questions in the proposed rule, particularly as the number and complexity of the applications have been increasing over time. That is, by making the applications available to the public online, we will afford more time for CMS to process and analyze the supporting data and evidence rather than reiterate parts of the application in the rule.

e. Permanent Cap on Wage Index Decreases

Consistent with section 1886(d)(3)(E) of the Act, we adjust the IPPS standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level and update the wage index annually based on a survey of wages and wage-related costs of short-term, acute care hospitals. As described in section III.N. of the preamble of this final rule, we have further considered the comments we received during the FY 2022 rulemaking recommending a permanent 5-percent cap policy to prevent large year-to-year variations in wage index values as a means to reduce overall volatility for hospitals. Under the authority at sections 1886(d)(3)(E) and 1886(d)(5)(I)(i) of the Act, for FY 2023 and subsequent years, we proposed to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, we proposed that a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We also proposed to apply the proposed wage index cap policy in a budget neutral manner through a national adjustment to the standardized amount under our authority in sections 1886(d)(3)(E) and 1886(d)(5)(I)(i) of the Act. As described in section III.N. of the preamble of this final rule, after consideration of the public comments received, we are finalizing these proposals without modification.

We note that the impact of not finalizing a 5 percent cap, or finalizing a higher cap, such as 10 percent, would be most marked for hospitals who have wage index changes of greater than 5 percent but less than the selected cap level, if any, in a given fiscal year. For example, in FY 2023 if the cap were 10 percent instead of 5 percent, approximately 12 hospitals would qualify vs approximately 125 hospitals under our adopted policy. The impact of finalizing a lower cap would be increases in payment to hospitals with wage index changes between a lower level and 5 percent, with a corresponding increase in the size of the budget neutrality adjustment for all hospitals.

f. Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low wage hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We also indicated our intention that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. As discussed in section III.G.4. of the preamble of this final rule, for FY 2023, we are continuing the low wage index hospital policy, and are also applying this policy in a budget neutral manner by applying an adjustment to the standardized amounts.

g. Application of the Rural Floor

As discussed in section III.G.1. of the preamble of this final rule, based on the district court's decision in *Citrus HMA, LLC, d/b/a Seven Rivers Regional Medical Center* v. *Becerra,* No. 1:20–cv–00707 (D.D.C.) and the comments we received, we are not finalizing our rural floor wage index policy as proposed, which would have excluded § 412.103 hospitals from the calculation of the rural floor and from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. Rather, we are finalizing a policy that calculates the rural floor as it was calculated before FY 2020. For FY 2023 and subsequent years, we are finalizing a policy to include the wage data of hospitals that have reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) and have no additional form of reclassification (MGCRB or Lugar) in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

The rural floor, which is budget neutral overall, increases payments to urban

hospitals whose wage index would otherwise be below the rural floor for their state. The policy we are adopting in section III.G.1. of the preamble of this final rule increases the rural floor in some states (for example, Arizona, Utah). This will generally increase payments to some urban hospitals in those states because their wage index will be higher than it otherwise would have been in the absence of this change. After application of the rural floor, we reduce the wage index of all hospitals by applying a budget neutrality factor to offset the increased payments. We note that there is either no increase in the rural floor or the increase in the rural floor is nominal in the majority of states, and the majority of hospitals will only experience payment decreases due to the effect of the increase in the budget neutrality adjustment.

h. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs)

In this final rule, as required by section 1886(r)(2) of the Act, we are updating our estimates of the three factors used to determine uncompensated care payments for FY 2023. We are finalizing our proposal to adopt a multiyear averaging methodology to determine Factor 3 of the uncompensated care payment methodology, which will help to mitigate against large fluctuations in uncompensated care payments from year to year. Specifically, we are using a 2-year average of audited data on uncompensated care costs from Worksheet S–10 from the FY 2018 and FY 2019 cost reports to calculate Factor 3 for FY 2023 for all eligible hospitals, including Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico. In addition, for FY 2024 and subsequent fiscal years, we will determine Factor 3 for all eligible hospitals using a 3-year average of the data on uncompensated care costs from Worksheet S–10 for the 3 most recent fiscal years for which audited data are available.

We recognize that discontinuing the use of the low-income insured days proxy to calculate Factor 3 in the uncompensated care payment methodology for IHS and Tribal hospitals and Puerto Rico hospitals could result in a significant financial disruption for these hospitals. Accordingly, we are also finalizing our proposal to use our authority under section 1886(d)(5)(I) of the Act to establish a new supplemental payment for these hospitals for FY 2023 and subsequent fiscal years. Refer to section I.H.2. of this Appendix for additional analysis on this new supplemental payment for FY 2023.

In the FY 2023 IPPS/LTCH PPS proposed rule, we proposed to revise our regulation governing the calculation of the Medicaid fraction of the DSH calculation with respect to the treatment of section 1115 demonstration days. As discussed in section IV.F. of the preamble of this final rule, we are not moving forward with the proposed revisions to the regulations relating to the treatment of section 1115 demonstration days for purposes of the DSH adjustment in this final rule. We expect to revisit the issue of section 1115 demonstration days in future rulemaking, and we encourage interested parties to review any future proposal on this issue and to submit their comments at that time.

i. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2023

The Rural Community Hospital Demonstration (RCHD) was authorized originally for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and it was extended for another 5-year period by section 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Section 15003 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255) extended the demonstration for an additional 5-year period, and section 128 of the Consolidated Appropriations Act of 2021(Pub. L. 116–159) included an additional 5-year re-authorization through 2028. CMS has conducted the demonstration since 2004, which allows enhanced, cost-based payment for Medicare inpatient services for up to 30 small rural hospitals.

The authorizing legislation imposes a strict budget neutrality requirement. In this final rule, we summarized the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality.

2. Payments for Graduate Medical Education (GME)

On May 17, 2021, the U.S. District Court for the District of Columbia ruled against CMS's method of calculating direct GME payments to teaching hospitals when those hospitals' weighted full-time equivalent (FTE) counts exceed their direct GME FTE cap. In *Milton S. Hershey Medical Center, et al.* v. *Becerra,* the court ordered CMS to recalculate reimbursement owed, holding that CMS's regulation impermissibly modified the statutory weighting factors.

After reviewing the statutory language regarding the direct GME FTE cap and the court's opinion in *Milton S. Hershey Medical Center, et al.* v. *Becerra,* we are finalizing, as described in greater detail in section V.F.2. of the preamble of this final rule, a modified policy to be applied retroactively and prospectively for all teaching hospitals. Specifically, effective for cost reporting periods beginning on or after October 1, 2001 that are open or reopenable, we specified that if the hospital's unweighted number of FTE residents exceeds the FTE cap, and the number of weighted FTE residents also exceeds that FTE cap, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the FTE cap. If the number of weighted FTE residents does not exceed that FTE cap, then the allowable weighted FTE count for direct GME payment is the actual weighted FTE count. We estimate the impact of this modified policy to be $170 million for FY 2023.

3. Frontier Community Health Integration Project (FCHIP) Demonstration

The Frontier Community Health Integration Project (FCHIP) demonstration was authorized under section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act (ACA) of 2010 (Pub. L. 114–158), and most recently re-authorized and extended by the Consolidated Appropriations Act of 2021 (Pub. L. 116–159). The legislation authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries in certain rural areas. The FCHIP demonstration initial period was conducted in 10 critical access hospitals (CAHs) from August 1, 2016, to July 31, 2019, and the demonstration ''extension period'' began on January 1, 2022, and run through June 30, 2027.

The authorizing legislation requires the FCHIP demonstration to be budget neutral. In this final rule, we will continue with the budget neutrality approach used in the demonstration initial period for the demonstration extension period—to offset payments across CAHs nationally—should the demonstration incur costs to Medicare.

4. Update to the LTCH PPS Payment Rates

As described in section VIII.C.2. of the preamble of this final rule, in order to update payments to LTCHs using the best available data, we updated the LTCH PPS standard Federal payment rate by 3.8 percent (that is, a 4.1 percent market basket update with a reduction of 0.3 percentage point for the productivity adjustment, as required by section 1886(m)(3)(A)(i) of the Act). LTCHs that failed to submit quality data, as required by 1886(m)(5)(A)(i) of the Act and described in section VIII.C.2. of the preamble of this final rule, will receive an update of 1.8 percent, which reflects a 2.0 percentage points reduction for failure to submit quality data.

5. Hospital Quality Programs

Section 1886(b)(3)(B)(viii) of the Act requires subsection (d) hospitals to report data in accordance with the requirements of the Hospital IQR Program for purposes of measuring and making publicly available information on health care quality, and links the quality data submission to the annual applicable percentage increase. Sections 1886(b)(3)(B)(ix), 1886(n), and 1814(l) of the Act require eligible hospitals and CAHs to demonstrate they are meaningful users of certified EHR technology for purposes of electronic exchange of health information to improve the quality of health care, and links the submission of information demonstrating meaningful use to the annual applicable percentage increase for eligible hospitals and the applicable percent for CAHs. Section 1886(m)(5) of the Act requires each LTCH to submit quality measure data in accordance with the requirements of the LTCH QRP for purposes of measuring and making publicly available information on health care quality, and in order to avoid a 2-percentage point reduction. Section 1886(o) of the Act requires the Secretary to establish a value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards established on an

announced set of quality and efficiency measures for the fiscal year. The purposes of the Hospital VBP Program include measuring the quality of hospital inpatient care, linking hospital measure performance to payment, and making publicly available information on hospital quality of care. Section 1886(p) of the Act requires a reduction in payment for subsection (d) hospitals that rank in the worst-performing 25 percent with respect to measures of hospital-acquired conditions under the HAC Reduction Program for the purpose of measuring, linking measure performance to payment, and making publicly available information on health care quality. Section 1886(q) of the Act requires a reduction in payment for subsection (d) hospitals for excess readmissions based on measures for applicable conditions under the Hospital Readmissions Reduction Program for the purpose of measuring, linking measure performance to payment, and making publicly available information on health care quality. Section 1866(k) of the Act applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') and requires PCHs to report data in accordance with the requirements of the PCHQR Program for purposes of measuring and making publicly available information on the quality of care furnished by PCHs, however, there is no reduction in payment to a PCH that does not report data.

6. Other Provisions

a. Codification of the Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans

As discussed in section X.A. of the preamble of this final rule, we codify in regulation certain general requirements; definitions; requirements for costs of the plans to be allowable under the program; additional requirements for payments to funded defined benefit plans; data and documentation requirements to support payments/contributions to the plans; and allowable administrative and other costs associated with the plans, including costs related to the Pension Benefit Guarantee Corporation.

b. Condition of Participation (CoP) Requirements for Hospitals and CAHs To Continue Reporting Data for COVID–19 and Influenza After the PHE Ends as Determined by the Secretary

Section X.B. of the preamble of this final rule revises the hospital and CAH infection prevention and control CoP requirements to require hospitals and CAHs, after the conclusion of the current COVID–19 PHE, to continue COVID–19 and seasonal influenza related reporting. The revisions will continue to apply upon conclusion of the COVID–19 PHE and will continue until April 30, 2024, unless the Secretary establishes an earlier ending date. In addition, as noted previously, we have withdrawn our proposal to establish additional data reporting requirements to address future PHEs related to epidemics and infectious diseases.

We believe these data will offer the most valuable information during a post-PHE state by continuing to capture critical data on COVID–19 for ongoing surveillance and to inform any potential action to protect patient health and safety. As previously discussed, these data will enable the federal government to monitor the ability of facilities to provide safe care for patients by determining the number of COVID–19 and influenza infections being treated by facilities; the quantity of resources available to facilities and the volume of resources they are using; and facilities' continued capacity to provide safe patient care. In addition, as done throughout the COVID–19 pandemic, local, state, and federal authorities will continue to use these data to identify possible resurgence in cases and outbreaks, for resource allocation purposes, and to update guidance pertaining to the safe provision of patient care.

As discussed in section X.B. of this rule, due to the unpredictable nature of the novel SARS–CoV–2 virus that causes COVID–19, in the event that the PHE declaration ends, we believe that continuing COVID–19-related data reporting through April 2024 is necessary to protect the health and safety of hospital and CAH patients as well as the communities in which the hospitals and CAHs are located. The COVID–19-related data reported by all hospitals and CAHs, have been, and continue to be, important in supporting surveillance of, and response to, COVID–19 and other respiratory illnesses. These data play an important role in evaluating spread of respiratory viruses and infections, including but not limited to COVID–19 and influenza. Retaining the data reporting requirements after the end of the current COVID–19 PHE is an important element of maintaining effective surveillance of this novel virus. Timely and actionable surveillance will enable CMS to continue to respond to facilities in need of additional technical support and oversight, should they experience increased cases or outbreaks of COVID–19 and/or influenza.

As noted, we do not expect continued daily reporting for COVID–19 or influenza outside of a declared PHE. Moreover, the rule allows for the scope of data categories and frequency of data collection and reporting to be reduced and limited, as determined by the Secretary, responsive to evolving clinical and epidemiology circumstances. These requirements will not be implemented and enforced until the current COVID–19 PHE declaration concludes, and CMS will issue guidance indicating such a transition. Reporting frequency and requirements will be communicated to hospitals, stakeholders, and the public following a model similar to that which we used to inform regulated entities at the beginning of the COVID–19 PHE (see *QSO–21–03–Hospitals/CAHs at https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0*). As discussed in section XII.B. of the preamble of this final rule, Collection of Information Requirements, we expect a burden increase of $38,204,400 or approximately $6,162 per facility annually for weekly reporting (an average response time of 1.5 hours per week for a registered nurse with an average hourly salary of $79). We note that efforts are underway to automate hospital and CAH reporting that have the potential to significantly decrease reporting burden and improve reliability.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these finalized regulations, and the Departments have provided the following assessment of their impact.

We estimate that the changes for FY 2023 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, will result in an estimated $1.4 billion increase in FY 2023 payments, primarily driven by: (a) a combined $2.4 billion increase in FY 2023 operating payments, including uncompensated care payments and supplemental payments; and (b) a combined decrease of $ 1.0 billion resulting from estimated changes in new technology add-on

payments, the change to the GME weighting methodology, the expiration of the low-volume payment adjustment, and FY 2023 capital payments. These changes are relative to payments made in FY 2022. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments by approximately $71 million in FY 2023 relative to FY 2022.

Our operating impact estimate includes the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this final rule. In addition, our operating payment impact estimate includes the 3.8 percent hospital update to the standardized amount (which includes the estimated 4.1 percent market basket update reduced by the 0.3 percentage point for the productivity adjustment). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule will affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Office of Management and Budget has reviewed this final rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this final rule contains a range of policies, we refer readers to the section of the final rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2023, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific policies in the discussion of those policies as needed.

E. Hospitals Included In and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 25 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland Total Cost of Care Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2022, there were 3,142 IPPS acute care hospitals included in our analysis. This represents approximately 53 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,425 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, cancer hospitals, extended neoplastic disease care hospital, and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this final rule. The impact of the final update and policy changes to the LTCH PPS for FY 2023 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2022, there were 92 children's hospitals, 11 cancer hospitals, 6 short term-acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, 1 extended neoplastic disease care hospital, and 14 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, the rehabilitation hospitals and units, and the LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and the psychiatric hospitals and units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this final rule. The impacts of the changes on LTCHs are discussed in section I.J. of this Appendix.

For the children's hospitals, cancer hospitals, short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2023 percentage increase in the 2018-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's second quarter 2022 forecast of the 2018-based IPPS market basket increase, we are estimating the FY 2023 update to be 4.1 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section V.A. of the preamble of this final rule. However, the Affordable Care Act requires a productivity adjustment (0.3 percentage point reduction for FY 2023), resulting in a 3.8 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section V.A. of the preamble of this rule. Children's hospitals, cancer hospitals, short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the 2018-based IPPS operating market basket for FY 2023, estimated at 4.1 percent.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this final rule, we are announcing policy changes and payment rate updates for the IPPS for FY 2023 for operating costs of acute care hospitals. The FY 2023 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2023 operating payments will increase by 2.6 percent, compared to FY 2022. In addition to the applicable percentage increase, this amount reflects the +0.5 percentage point permanent adjustment to the standardized amount required under section 414 of MACRA. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall payment changes.

We have prepared separate impact analyses of the changes to each system. This section deals with the changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the best available claims data to enable us to estimate the impacts on payments per case of certain changes in this final rule. As discussed in section I.F of this final rule, we believe that the FY 2021 claims data is the best available data for purposes of the FY 2023 ratesetting and this impact analysis reflects the use of that data. However, there are other changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented in this section are taken from the FY 2021 MedPAR file, as discussed previously in this final rule, and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the operating PPS do not incorporate cost data, data from the best available hospital cost reports were used to categorize hospitals, as also discussed previously in this final rule. Our analysis has several qualifications. First, in this analysis, we do not adjust for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2021 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, and the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2023 are discussed in section I.I. of this Appendix.

We discuss the following changes:

- The effects of the application of the applicable percentage increase of 3.8 percent (that is, a 4.1 percent market basket update with a reduction of 0.3 percentage point for the productivity adjustment), and a 0.5 percentage point adjustment required under section 414 of the MACRA to the IPPS standardized amount, and the applicable percentage increase (including the market basket update and the productivity adjustment) to the hospital-specific rates.
- The effects of the changes to the relative weights and MS–DRG GROUPER.
- The effects of the changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2019, compared to the FY 2018 wage data, to calculate the FY 2023 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this final rule) that will be effective for FY 2023.
- The effects of the rural floor with the application of the national budget neutrality factor to the wage index.
- The effects of the imputed floor wage index adjustment. This provision is not budget neutral.
- The effects of the frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes for FY 2023. This provision is not budget neutral.
- The effects of the expiration of the special payment status for MDHs at the end of FY 2022 under current law as a result of which MDHs that currently receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate plus 75 percent of the difference between payments based on the Federal rate and the hospital-specific rate will be paid based on the Federal rate starting in FY 2023.
- The total estimated change in payments based on the FY 2023 policies relative to payments based on FY 2022 policies.

To illustrate the impact of the FY 2023 changes, our analysis begins with a FY 2022 baseline simulation model using: the FY 2022 applicable percentage increase of 2.0 percent; the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount; the FY 2022 MS–DRG GROUPER (Version 39); the FY 2022 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2022 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner, and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 2.775 percent. At the time this impact was prepared, 24 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2023 because they failed the quality data submission process or did not choose to participate, but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the payment changes for FY 2023 using a reduced update for these hospitals.

For FY 2023, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of 0.725 percent. At the time this impact analysis was prepared, 158 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2023 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the payment changes for FY 2023 using a reduced update for these hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of -0.3 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time this impact was prepared, 20 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2023 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2023 model incorporating all of the changes. This simulation allows us to isolate the effects of each change.

Our comparison illustrates the percent change in payments per case from FY 2022 to FY 2023. Two factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are updating the standardized amounts for FY 2023 using an applicable percentage increase of 3.8 percent. This includes the FY 2023 forecasted IPPS operating hospital market basket increase of 4.1 percent with a 0.3 percentage point reduction for the productivity adjustment. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users will receive a update of 2.775 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users will receive an update of 0.725 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive an update of −0.3 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs is also equal to the applicable percentage increase, or 3.8 percent, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the changes in hospitals' payments per case from FY 2022 to FY 2023 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2022 that are no longer reclassified in FY 2023. Conversely, payments may increase for hospitals not reclassified in FY 2022 that are reclassified in FY 2023.

2. Analysis of Table I

Table I displays the results of our analysis of the changes for FY 2023. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,142 acute care hospitals included in the analysis.

The next two rows of Table I contain hospitals categorized according to their geographic location: urban and rural. There are 2,420 hospitals located in urban areas and 722 hospitals in rural areas included in our analysis. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2023 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 1,861, and 1,281, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 1,939 nonteaching hospitals in our analysis, 929 teaching hospitals with fewer than 100 residents, and 274 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next six rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs and RRCs) and reclassification status from urban to rural in accordance with section 1886(d)(8)(E) of the Act. Of the hospitals that are not reclassified from urban to rural, there are 148 RRCs, 256 SCHs, and 122 hospitals that are both SCHs and RRCs. Of the hospitals that are reclassified from urban to rural, there are 470 RRCs, 47 SCHs, and 39 hospitals that are both SCHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare and Medicaid utilization expressed as a percent of total inpatient days. These data were taken from the most recent available Medicare cost reports.

The next grouping is based on hospitals' reporting of diagnosis codes describing patients experiencing homelessness. This row reflects hospitals whose claims indicate that at least 5 percent of their IPPS cases involve these patients based on the reporting of ICD–10–CM diagnosis code Z59.0 (Homelessness). We note that hospitals are not required to identify these patients on their claims, and reporting this information on the claim does not currently impact Medicare payment. There may be other hospitals with at least 5 percent of their IPPS cases involving these patients, however we are unable to identify these hospitals. We refer the reader to Section II.D.13.d. of this FY 2023 IPPS/LTCH PPS final rule for discussion of the comments we received in response to our request for information on the reporting of social determinants of health diagnosis codes, such as diagnosis code Z59.0 (Homelessness), in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28177).

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2023 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act.

TABLE I.—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2023

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All FY 2023 Changes (8)[9]
All Hospitals	3,142	4.2	0.0	0.0	0.0	0.0	0.3	-0.2	2.6
By Geographic Location:									
Urban hospitals	2,420	4.3	0.0	0.0	-0.1	0.0	0.3	-0.1	2.6
Rural hospitals	722	4.0	0.1	0.0	1.0	-0.2	0.1	-0.7	2.4
Bed Size (Urban):									
0-99 beds	653	4.2	0.0	0.0	-0.8	0.2	0.6	-1.6	1.1
100-199 beds	700	4.3	0.2	0.0	-0.1	0.2	0.3	-0.3	2.9
200-299 beds	411	4.3	0.1	0.0	0.1	0.0	0.3	0.0	3.0
300-499 beds	409	4.3	0.0	0.0	0.1	0.0	0.3	0.0	2.7
500 or more beds	245	4.2	-0.1	0.0	-0.2	0.0	0.2	0.0	2.4
Bed Size (Rural):									
0-49 beds	358	3.8	0.0	-0.1	0.5	-0.3	0.2	-1.6	0.9
50-99 beds	201	3.9	0.2	0.0	0.6	-0.2	0.3	-1.7	1.3
100-149 beds	84	4.0	0.3	0.0	1.3	-0.2	0.0	-0.1	3.5
150-199 beds	46	4.1	0.1	-0.1	1.0	-0.2	0.1	0.0	3.1
200 or more beds	33	4.0	0.1	0.2	1.6	-0.3	0.0	0.0	3.4
Urban by Region:									
New England	107	4.2	-0.1	-0.4	1.8	3.8	0.7	-0.2	3.2
Middle Atlantic	295	4.3	0.1	0.1	0.5	-0.4	0.4	-0.1	2.5
East North Central	373	4.3	-0.1	-0.2	-0.3	-0.4	0.1	-0.3	2.3
West North Central	156	4.2	-0.2	-0.3	-0.7	-0.4	0.8	0.0	2.2
South Atlantic	402	4.3	0.0	-0.2	-0.7	-0.4	0.3	-0.1	2.4
East South Central	140	4.3	0.1	-0.2	-0.7	-0.4	0.0	0.0	2.5
West South Central	362	4.3	0.1	0.4	-0.7	-0.4	0.0	-0.1	3.0
Mountain	176	4.2	-0.1	-0.1	0.2	1.1	0.3	0.0	4.1
Pacific	359	4.2	0.1	0.5	0.3	0.0	0.1	0.0	2.4
Puerto Rico	50	4.3	0.6	-0.5	-1.3	0.4	0.1	0.0	3.8
Rural by Region:									
New England	19	4.1	-0.2	0.6	-0.1	-0.3	0.2	-1.7	0.1
Middle Atlantic	49	4.1	0.0	-0.2	1.3	-0.2	0.0	-0.6	2.5
East North Central	113	4.0	-0.1	-0.2	1.2	-0.2	0.0	-2.5	0.1
West North Central	86	3.7	0.0	0.2	-0.1	-0.1	0.2	-0.3	2.9
South Atlantic	109	4.0	0.4	0.0	1.5	-0.2	0.1	-0.1	3.6
East South Central	141	4.1	0.4	-0.1	1.4	-0.3	0.1	-0.2	3.2
West South Central	134	4.0	0.3	0.4	1.5	-0.3	0.0	-0.4	2.8
Mountain	47	3.2	0.0	-0.7	0.1	-0.2	1.2	0.0	2.8
Pacific	24	3.9	0.2	-0.1	0.9	-0.1	0.0	0.0	3.4
By Payment Classification:									
Urban hospitals	1,861	4.3	0.0	0.0	-0.8	-0.1	0.3	0.0	2.5
Rural areas	1,281	4.2	0.0	0.0	0.9	0.1	0.2	-0.3	2.7
Teaching Status:									
Nonteaching	1,939	4.2	0.1	0.1	0.0	0.1	0.2	-0.4	2.6
Fewer than 100 residents	929	4.3	0.0	0.0	0.0	-0.1	0.3	-0.1	2.6

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All FY 2023 Changes (8)[9]
100 or more residents	274	4.2	0.0	0.0	0.0	0.0	0.2	0.0	2.5
Urban DSH:									
Non-DSH	369	4.3	-0.3	0.1	-0.3	-0.2	0.5	-0.2	2.3
100 or more beds	1,129	4.3	0.1	0.0	-0.8	-0.1	0.3	0.0	2.5
Less than 100 beds	363	4.3	0.3	0.1	-0.7	0.3	0.5	-0.4	2.7
Rural DSH:									
Non-DSH	105	4.2	-0.2	-0.3	1.2	1.1	0.2	-1.7	1.7
SCH	264	3.8	0.1	0.0	0.1	0.0	0.1	0.0	3.8
RRC	674	4.2	0.0	0.0	0.9	0.1	0.2	-0.1	2.8
100 or more beds	22	4.4	0.0	0.1	-0.1	1.1	0.0	-3.4	0.1
Less than 100 beds	216	4.2	0.1	0.0	1.1	-0.5	0.2	-4.8	-4.0
Urban teaching and DSH:									
Both teaching and DSH	663	4.3	0.0	0.0	-0.8	-0.2	0.4	0.0	2.5
Teaching and no DSH	60	4.3	-0.4	0.2	0.2	-0.1	0.5	-0.3	2.0
No teaching and DSH	829	4.3	0.2	0.0	-0.7	0.1	0.2	0.0	2.7
No teaching and no DSH	309	4.3	-0.3	0.1	-0.6	-0.2	0.6	-0.1	2.5
Special Hospital Types:									
RRC	148	4.4	0.1	-0.1	1.5	-0.2	0.3	-0.7	2.0
RRC with Section 401 Rural Reclassification	470	4.2	-0.1	0.0	1.0	0.2	0.2	-0.1	2.8
SCH	256	3.7	0.1	0.0	0.0	0.0	0.1	0.0	3.6
SCH with Section 401 Rural Reclassification	47	3.7	0.0	0.0	0.0	0.1	0.0	0.0	3.8
SCH and RRC	122	3.8	0.1	0.0	0.3	-0.1	0.0	0.0	3.5
SCH and RRC with Section 401 Rural Reclassification	39	3.9	-0.3	0.0	0.1	-0.1	0.0	0.0	3.3
Type of Ownership:									
Voluntary	1,915	4.3	0.0	0.0	0.1	0.0	0.3	-0.2	2.5
Proprietary	789	4.2	0.2	0.0	-0.1	0.1	0.2	-0.1	3.3
Government	438	4.1	0.1	0.1	-0.4	-0.2	0.1	-0.1	2.4
Medicare Utilization as a Percent of Inpatient Days:									
0-25	790	4.2	0.1	0.1	-0.4	-0.2	0.1	0.0	2.9
25-50	2,072	4.2	0.0	0.0	0.1	0.0	0.3	-0.2	2.5
50-65	225	4.2	0.1	0.1	-0.1	0.6	0.4	-0.3	2.8
Over 65	30	3.1	-1.1	-0.5	-0.7	-0.4	0.0	-1.1	0.3
Medicaid Utilization as a Percent of Inpatient Days:									
0-25	2,082	4.2	-0.1	0.0	0.1	-0.1	0.3	-0.3	2.4
25-50	942	4.2	0.1	0.0	-0.1	0.1	0.3	0.0	2.8
50-65	94	4.1	0.9	0.4	-0.7	0.5	0.2	0.0	3.5
Over 65	24	4.1	1.0	1.2	-0.9	-0.3	0.1	0.0	4.4
Hospitals with 5% or more of cases that reported experiencing homelessness	45	4.2	1.0	0.5	-0.7	-0.2	0.2	0.0	3.9
FY 2023 Reclassifications:									
All Reclassified Hospitals	1,004	4.2	0.0	0.0	1.2	0.1	0.1	-0.1	2.8
Non-Reclassified Hospitals	2,138	4.3	0.0	0.0	-1.1	-0.1	0.4	-0.2	2.4
Urban Hospitals Reclassified	840	4.2	-0.1	0.0	1.1	0.1	0.2	-0.2	2.7
Urban Non-Reclassified Hospitals	1,594	4.3	0.0	0.0	-1.3	-0.1	0.4	0.0	2.5
Rural Hospitals Reclassified Full Year	282	4.1	0.2	-0.1	1.9	-0.2	0.1	-0.5	2.8

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All FY 2023 Changes (8)[9]
Rural Non-Reclassified Hospitals Full Year	426	3.8	0.1	0.1	-0.5	-0.2	0.2	-0.9	1.9
All Section 401 Rural Reclassified Hospitals	615	4.2	-0.1	0.0	0.9	0.2	0.2	-0.2	2.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	4.2	0.2	0.0	3.0	-0.4	0.2	-2.0	0.6

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2021, and hospital cost report data are from the latest available reporting periods.

[2] This column displays the payment impact of the hospital rate update and other adjustments, including the 3.8 percent update to the national standardized amount and the hospital-specific rate (the 4.1 percent market basket update reduced by 0.3 percentage point for the productivity adjustment), and the 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the changes to the Version 40 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2021 MedPAR data as the best available data, and the permanent 10-percent cap where the relative weight for a MS-DRG would decrease by more than 10 percent in a given fiscal year. This column displays the application of the recalibration budget neutrality factors of 1.000509and 0.999764.

[4] This column displays the payment impact of the update to wage index data using FY 2019 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor. The wage budget neutrality factor is 1.000968.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2023 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2023. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.984399.

[6] This column displays the effects of the rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index is 0.991909.

[7] This column shows the combined impact of (1) the imputed floor for all-urban states (2) the policy that requires hospitals located in frontier States have a wage index no less than 1.0; and (3) the policy which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column displays the impact of the expiration of MDH status for FY 2023, a non-budget neutral payment provision.

[9] This column shows the estimated change in payments from FY 2022 to FY 2023.

a. Effects of the Hospital Update and Other Adjustments (Column 1)

As discussed in section V.A. of the preamble of this final rule, this column includes the hospital update, including the 4.1 percent market basket update reduced by the 0.3 percentage point for the productivity adjustment. In addition, as discussed in section II.D. of the preamble of this final rule, this column includes the FY 2023 +0.5 percentage point adjustment required under section 414 of the MACRA. As a result, we are making a 4.3 percent update to the national standardized amount. This column also includes the update to the hospital-specific rates which includes the 4.1 percent market basket update reduced by the 0.3 percentage point for the productivity adjustment. As a result, we are making a 3.8 percent update to the hospital-specific rates.

Overall, hospitals will experience a 4.2 percent increase in payments primarily due to the combined effects of the hospital update to the national standardized amount and the hospital update to the hospital-specific rate. Hospitals that are paid under the hospital-specific rate will experience a 3.8 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital-specific rate will experience a lower than average increase in payments.

b. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral. As discussed in section VIII.B.3.b. of the preamble of this final rule, we are also establishing a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given year and an associated recalibration cap budget neutrality factor to account for the 10-percent cap on relative weight reductions to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this final rule, the FY 2023 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2023, we are calculating the MS–DRGs using the FY 2021 MedPAR data grouped to the Version 40 (FY 2023) MS–DRGs. The reclassification changes to the GROUPER are described in more detail in section II.D. of the preamble of this final rule.

The ''All Hospitals'' line in Column 2 indicates that changes due to the MS–DRGs and relative weights will result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 1.000509 and the recalibration cap budget neutrality factor of 0.999764 to the standardized amount.

c. Effects of the Wage Index Changes (Column 3)

Column 3 shows the impact of the updated wage data, with the application of the wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2023 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01), as updated in OMB Bulletin Nos. 15–01, 17–01, 18–04, and 20–01. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations, based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index; to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913) for a discussion of our adoption of the CBSA updates in OMB Bulletin No. 15–01, which were effective beginning with the FY 2017 wage index; to the FY 2020 IPPS/LTCH PPS final rule (83 FR 41362) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 17–01 for the FY 2020 wage index; to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 18–04 for the FY 2021 wage index; and to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45163) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 20–01 for the FY 2022 wage index.)

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the wage index for acute care hospitals for FY 2023 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2018 and before October 1, 2019. The estimated impact of the updated wage data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the percentage change in payments when going from a model using the FY 2022 wage index, the labor-related share of 67.6 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2023 pre-reclassification wage index with the labor-related share of 67.6 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters, such as use of the Version 40 MS–DRG GROUPER constant. The FY 2023 occupational mix adjustment is based on the CY 2019 occupational mix survey.

In addition, the column shows the impact of the application of the wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2023, as proposed, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 67.6 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The FY 2023 wage budget neutrality factor is 1.000968 and the overall payment change is 0 percent.

Column 3 shows the impacts of updating the wage data. Overall, the new wage data and the labor-related share, combined with the wage budget neutrality adjustment, will lead to no change for all hospitals, as shown in Column 3.

In looking at the wage data itself, the national average hourly wage will increase 2.7 percent compared to FY 2022. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the 2.7 percent increase in the national average hourly wage. Of the 3,117 hospitals with wage data for both FYs 2022 and 2023, 1,427 or 45.8 percent will experience an average hourly wage increase of 2.7 percent or more.

The following table compares the shifts in wage index values for hospitals due to changes in the average hourly wage data for FY 2023 relative to FY 2022. These figures reflect changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this final rule) is used to adjust the labor-related share of a hospital's standardized amount, either 67.6 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the pre-reclassified wage index figures in the following table may illustrate a somewhat larger or smaller change than will occur in a hospital's payment wage index and total payment.

The following table shows the projected impact of changes in the area wage index values for urban and rural hospitals.

FY 2023 Percentage Change in Area Wage Index Values	Number of Hospitals	
	Urban	Rural
Increase 10 percent or more	2	0
Increase greater than or equal to 5 percent and less than 10 percent	24	0
Increase or decrease less than 5 percent	2,330	706
Decrease greater than or equal to 5 percent and less than 10 percent	48	7
Decrease 10 percent or more	0	0
Unchanged	1	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2023.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials by the MGCRB of reclassification requests to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year (we refer readers to the discussion of our clarification of this policy in section III.I.2. of the preamble of this final rule.)

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, as proposed, we are applying an adjustment of 0.984399 to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this final rule).

Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification will increase payments to rural hospitals by an average of 1.0 percent. By region, most rural hospital categories will experience increases in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website reflects the reclassifications for FY 2023.

e. Effects of the Rural Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011 through 2022 IPPS/LTCH PPS final rules, and this FY 2023 IPPS/LTCH PPS final rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same state. We apply a uniform budget neutrality adjustment to the wage index. Column 5 shows the effects of the rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated an FY 2023 rural floor budget neutrality factor to be applied to the wage index of 0.991909, which would reduce wage indexes by 0.8 percent.

Column 5 shows the projected impact of the rural floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the post-reclassification FY 2023 wage index of providers before the rural floor adjustment and the post-reclassification FY 2023 wage index of providers with the rural floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural floor. Because the provision is budget neutral, all other hospitals that do not receive an increase to their wage index from the rural floor adjustment (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the budget neutrality adjustment that is applied to the wage index nationally. (As discussed in section III.G.1. of the preamble of this final rule, based on the district court's decision in *Citrus,* we calculated the rural floor for FY 2023 including the wage data of hospitals that have reclassified as rural under § 412.103.)

We estimate that 275 hospitals will receive the rural floor in FY 2023. All IPPS hospitals in our model will have their wage indexes reduced by the rural floor budget neutrality adjustment of 0.991909. We project that, in aggregate, rural hospitals will experience a 0.2 percent decrease in payments as a result of the application of the rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project that, in the aggregate, hospitals located in urban areas will experience no change in payments because increases in payments to hospitals benefitting from the rural floor offset decreases in payments to nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region would experience a 3.8 percent increase in payments primarily due to the application of the rural floor in Massachusetts.

f. Effects of the Application of the Imputed Floor, Frontier State Wage Index and Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of the following: (1) the imputed floor under section 1886(d)(3)(E)(iv)(I) and (II) of the Act, which provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018; (2) section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States;'' and (3) the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index.

These three wage index provisions are not budget neutral and will increase payments overall by 0.3 percent compared to the provisions not being in effect.

Section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index for all-urban States shall not be applied in a budget neutral manner. Therefore, the imputed floor adjustment is estimated to increase IPPS operating payments by approximately $124 million. There are an estimated 66 providers in Connecticut, Delaware, Washington DC, New Jersey, and Rhode Island that will receive the imputed floor wage index.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and an estimated 44 hospitals located in Montana, North Dakota, South Dakota, and Wyoming would receive a frontier wage index of 1.0000. We note, the rural floor for Nevada exceeds the frontier state wage index of 1.000

and therefore no hospitals in Nevada receive the frontier state wage index. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $71 million.

In addition, section 1886(d)(13) of the Act provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment will receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 210 providers that will receive the out-migration wage adjustment in FY 2023. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase will be approximately $53 million.

g. Effects of the Expiration of MDH Special Payment Status (Column 7)

Column 7 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision. Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted on February 9, 2018) extended the MDH program (which, under previous law, was to be in effect for discharges before October 1, 2017 only) for discharges occurring on or after October 1, 2017, through FY 2022 (that is, for discharges occurring on or before September 30, 2022). Therefore, under current law, the MDH program will expire at the end of FY 2022. Hospitals that qualified to be MDHs receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate amount plus 75 percent of the difference between payments based on the Federal rate and payments based on the hospital-specific rate (a hospital-specific cost-based rate). Because this provision was not budget neutral, the expiration of this payment provision results in a 0.2 percent decrease in payments overall. There are currently 173 MDHs, of which we estimate 91 would have been paid under the blended payment of the Federal rate and hospital-specific rate if the MDH program had not expired. Because those 91 MDHs will no longer receive the blended payment and will be paid only under the Federal rate in FY 2023, it is estimated that those hospitals would experience an overall decrease in payments of approximately $180 million.

h. Effects of All FY 2022 Changes (Column 8)

Column 8 shows our estimate of the changes in payments per discharge from FY 2022 and FY 2023, resulting from all changes reflected in this rule for FY 2023. It includes combined effects of the year-to-year change of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 2.6 percent for FY 2023 relative to FY 2022 and for this row is primarily driven by the changes reflected in Column 1. Column 8 includes the annual hospital update of 3.8 percent to the national standardized amount. This annual hospital update includes the 4.1 percent market basket update reduced by the 0.3 percentage point productivity adjustment. As discussed in section II.D. of the preamble of this final rule, this column also includes the +0.5 percentage point adjustment required under section 414 of the MACRA. Hospitals paid under the hospital-specific rate would receive a 3.8 percent hospital update. As described in Column 1, the annual hospital update with the +0.5 percent adjustment for hospitals paid under the national standardized amount, combined with the annual hospital update for hospitals paid under the hospital-specific rates, combined with the other adjustments described previously and shown in Table I, will result in a 2.6 percent increase in payments in FY 2023 relative to FY 2022.

This column also reflects the estimated effect of outlier payments returning to their targeted levels in FY 2023 as compared to the estimated outlier payments for FY 2022 produced from our payment simulation model. As discussed in section II.A.4.j. of the Addendum to this final rule, the statute requires that outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments, and also requires that the average standardized amount be reduced by a factor to account for the estimated proportion of total DRG payments made to outlier cases. As proposed, we are continuing to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount, just as we did for FY 2022. Therefore, our estimate of payments per discharge for FY 2023 from our payment simulation model reflects this 5.1 percent outlier payment target. Our payment simulation model shows that estimated outlier payments for FY 2022 exceed that target by approximately 1.7 percent. Therefore, our estimate of the changes in payments per discharge from FY 2022 and FY 2023 in Column 8 reflects the estimated -1.7 percent change in outlier payments produced by our payment simulation model when returning to the 5.1 percent outlier target for FY 2023. There are also interactive effects among the various factors comprising the payment system that we are not able to isolate, which may contribute to our estimate of the changes in payments per discharge from FY 2022 and FY 2023 in Column 8.

Overall payments to hospitals paid under the IPPS due to the applicable percentage increase and proposed changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 2.6 percent for FY 2023. Hospitals in urban areas will experience a 2.6 percent increase in payments per discharge in FY 2023 compared to FY 2022. Hospital payments per discharge in rural areas are estimated to increase by 2.4 percent in FY 2023.

3. Impact Analysis of Table II

Table II presents the projected impact of the changes for FY 2023 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2022 with the estimated average payments per discharge for FY 2023, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 8 of Table I.

TABLE II.--IMPACT ANALYSIS OF CHANGES FOR FY 2023 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of Hospitals (1)	Estimated Average FY 2022 Payment Per Discharge (2)	Estimated Average FY 2023 Payment Per Discharge (3)	FY 2023 Changes (4)
All Hospitals	3,142	15,064	15,453	2.6
By Geographic Location:				
Urban hospitals	2,420	15,450	15,852	2.6
Rural hospitals	722	11,264	11,530	2.4
Bed Size (Urban):				
0-99 beds	653	11,638	11,761	1.1
100-199 beds	700	12,336	12,693	2.9
200-299 beds	411	13,921	14,345	3
300-499 beds	409	15,259	15,677	2.7
500 or more beds	245	19,035	19,492	2.4
Bed Size (Rural):				
0-49 beds	358	9,656	9,743	0.9
50-99 beds	201	10,973	11,118	1.3
100-149 beds	84	10,930	11,312	3.5
150-199 beds	46	12,354	12,740	3.1
200 or more beds	33	12,935	13,372	3.4
Urban by Region:				
New England	107	16,943	17,480	3.2
Middle Atlantic	295	18,132	18,590	2.5
East North Central	373	14,666	15,001	2.3
West North Central	156	14,816	15,140	2.2
South Atlantic	402	13,341	13,659	2.4
East South Central	140	12,824	13,147	2.5
West South Central	362	13,506	13,915	3
Mountain	176	15,343	15,965	4.1
Pacific	359	19,835	20,305	2.4
Puerto Rico	50	9,110	9,461	3.8
Rural by Region:				
New England	19	16,103	16,125	0.1
Middle Atlantic	49	11,001	11,281	2.5
East North Central	113	11,471	11,487	0.1
West North Central	86	11,804	12,144	2.9
South Atlantic	109	10,381	10,759	3.6
East South Central	141	10,144	10,464	3.2
West South Central	134	9,730	10,002	2.8
Mountain	47	13,126	13,500	2.8
Pacific	24	15,534	16,066	3.4
By Payment Classification:				
Urban hospitals	1,861	14,338	14,700	2.5
Rural areas	1,281	15,990	16,414	2.7
Teaching Status:				
Nonteaching	1,939	11,851	12,156	2.6
Fewer than 100 residents	929	13,898	14,266	2.6
100 or more residents	274	21,998	22,553	2.5
Urban DSH:				
Non-DSH	369	12,491	12,782	2.3
100 or more beds	1,129	14,828	15,205	2.5
Less than 100 beds	363	10,749	11,039	2.7
Rural DSH:				
Non-DSH	105	14,163	14,405	1.7
SCH	264	12,442	12,911	3.8
RRC	674	16,726	17,198	2.8
100 or more beds	22	13,264	13,279	0.1
Less than 100 beds	216	9,297	8,921	-4
Urban teaching and DSH:				
Both teaching and DSH	663	16,060	16,456	2.5
Teaching and no DSH	60	14,060	14,345	2

	Number of Hospitals (1)	Estimated Average FY 2022 Payment Per Discharge (2)	Estimated Average FY 2023 Payment Per Discharge (3)	FY 2023 Changes (4)
No teaching and DSH	829	12,077	12,409	2.7
No teaching and no DSH	309	11,689	11,983	2.5
Special Hospital Types:				
RRC	148	11,620	11,848	2
RRC with Section 401 Rural Reclassification	470	17,565	18,057	2.8
SCH	256	11,626	12,045	3.6
SCH with Section 401 Rural Reclassification	47	14,462	15,009	3.8
SCH and RRC	122	13,174	13,637	3.5
SCH and RRC with Section 401 Rural Reclassification	39	15,623	16,137	3.3
Type of Ownership:				
Voluntary	1,915	15,141	15,515	2.5
Proprietary	789	13,173	13,613	3.3
Government	438	17,122	17,540	2.4
Medicare Utilization as a Percent of Inpatient Days:				
0-25	790	17,643	18,155	2.9
25-50	2,072	14,501	14,858	2.5
50-65	225	12,154	12,496	2.8
Over 65	30	9,588	9,614	0.3
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	2,082	13,649	13,980	2.4
25-50	942	17,466	17,949	2.8
50-65	94	20,166	20,872	3.5
Over 65	24	21,038	21,971	4.4
Hospitals with 5% or more of cases that reported experiencing homelessness	45	19,202	19,952	3.9
FY 2023 Reclassifications:				
All Reclassified Hospitals	1,004	15,971	16,418	2.8
Non-Reclassified Hospitals	2,138	14,291	14,631	2.4
Urban Hospitals Reclassified	840	16,472	16,913	2.7
Urban Nonreclassified Hospitals	1,594	14,488	14,851	2.5
Rural Hospitals Reclassified Full Year	282	11,381	11,697	2.8
Rural Non-Reclassified Hospitals Full Year	426	11,120	11,328	1.9
All Section 401 Reclassified Hospitals:	615	17,132	17,590	2.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	10,488	10,554	0.6

H. Effects of Other Policy Changes

In addition to those policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are making various other changes in this final rule. As noted in section I.D. of this Appendix A, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes using that payment simulation model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other changes are discussed in this section.

1. Effects of Policy Changes Relating to New Medical Service and Technology Add-On Payments

a. FY 2023 Status of Technologies Approved for FY 2022 New Technology Add-On Payments

As discussed in section II.F.5.a. of the preamble of this final rule, we are continuing new technology add-on payments in FY 2023 for the 15 technologies that are still within their newness period. Under § 412.88(a)(2), the new technology add-on payment for each case involving use of an approved technology would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as Qualified Infectious Disease Products (QIDPs) or approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs or approved under the LPAD pathway). Because it is difficult to predict the actual new technology add-on payment for each case, the estimated total payments in this final rule are based on the applicant's estimated cost and volume projections at the time they submitted their original application (unless the applicant provided updated figures in a public comment) and the assumption that every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment.

In the following table, we present estimated total payments for the 15 technologies for which we are continuing to make new technology add-on payments in FY 2023:

FY 2023 Estimates for Technologies Approved for New Technology Add-On Payments in FY 2022			
Technology Name	**Estimated Cases**	**FY 2023 NTAP Amount (65 % or 75 %)**	**Estimated Total FY 2023 Impact**
Rybrevant™	349	$6,405.89	$2,235,655.61
Cosela™	435	$5,612.10	$2,441,263.50
ABECMA®	484	$289,532.75	$140,133,851.00
StrataGraft®	261	$44,200.00	$11,536,200.00
TECARTUS®	15	$259,350.00	$3,890,250.00
VEKLURY®	174,996	$2,028.00	$354,891,888.00
Zepzelca™	778	$9,145.50	$7,115,199.00
aprevo® Intervertebral Body Fusion Device	1,261	$40,950.00	$51,637,950.00
aScope® Duodeno	3,750	$1,296.75	$4,862,812.50
Caption Guidance™	2,592	$1,868.10	$4,842,115.20
Harmony™ Transcatheter Pulmonary Valve (TPV) System	171	$26,975.00	$4,612,725.00
Intercept®	2,296	$2,535.00	$5,820,360.00
ShockWave C2 Intravascular Lithotripsy (IVL) System	3,760	$3,666.00	$13,784,160.00
Fetroja® (HABP/VABP)	379	$8,579.84	$3,251,759.36
Recarbrio™ (HABP/VABP)	928	$9,576.51	$8,887,001.28
Aggregate Estimated Total FY 2023 Impact			**$619,943,190.45**

b. FY 2023 Applications for New Technology Add-On Payments

In sections II.F.6. and 7. of the preamble to this final rule, we discussed 11 technologies for which we received applications for new technology add-on payments for FY 2023. We noted that of the 37 applications (19 alternative and 18 traditional) we received, 23 applicants withdrew their application (11 alternative and 12 traditional) prior to the issuance of this final rule, and 3 technologies (2 alternative and 1 traditional) did not meet the July 1 deadline for FDA approval or clearance of the technology and were therefore ineligible for consideration for new technology add-on payments for FY 2023. As explained in the preamble to this final rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral.

As discussed in section II.F.7. of the preamble of this final rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation, approved through the FDA LPAD pathway, or are part of the Breakthrough Device program will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still be within the 2–3 year newness period, as discussed in II.F.1.a.(1) of this final rule, and must also still meet the cost criterion.

As fully discussed in section II.F.7. of the preamble of this final rule, we are approving or conditionally approving 6 alternative pathway applications for FY 2023 new technology add-on payments, including 5 technologies that received a Breakthrough Device designation from FDA and 1 that was designated as a QIDP by FDA. Based on information from the applicants at the time of the final rule, we estimate that total payments for the 6 technologies approved under the alternative pathway will be approximately $88.45 million for FY 2023. Total estimated FY 2023 payments for new technologies that are designated as a QIDP are approximately $33.9 million, and total estimated FY 2023 payments for new technologies that are part of the Breakthrough Device program are approximately $54.6 million.

In the following table, we present detailed estimates for the six technologies for which we are approving new technology add-on payments under the alternative pathway in FY 2023:

FY 2023 Estimates for New Technology Add-On Payments for Technologies under the Alternative Pathway for FY 2023				
Technology Name	**Pathway (QIDP, LPAD, or Breakthrough Device)**	**Estimated Cases**	**FY 2023 NTAP Amount (65 % or 75 %)**	**Estimated Total FY 2023 Impact**
Cerament® G	Breakthrough Device	1610	$4,918.55	$7,918,865.50
GORE TAG Thoracic Branch Endoprosthesis	Breakthrough Device	386	$27,807.00	$10,733,502.00
iFuse Bedrock Granite Implant System	Breakthrough Device	1,480	$9,828.00	$14,545,440.00
Thoraflex Hybrid Device	Breakthrough Device	800	$22,750.00	$18,200,000.00
ViviStim	Breakthrough Device	135	$23,400.00	$3,159,000.00
DefenCath	QIDP	7726	$4,387.50	$33,897,825.00
Estimated Total FY 2023 Impact				**$88,454,632.50**

As fully discussed in section II.F.6. of the preamble of this final rule, we are approving three technologies that applied under the traditional pathway for new technology add-on payments for FY 2023, and providing new technology add-on payments for one application that is substantially similar to a current NTAP-approved technology. Based on information from the applicants at the time of rulemaking, we estimate that total payments for the four technologies for which we are making new technology add-on payments is approximately $75.16 million for FY 2023.

In the following table, we present detailed estimates for the four technologies for which we are providing new technology add-on payments under the traditional pathway in FY 2023:

FY 2023 Estimates for New Technology Add-On Payments for Technologies under the Traditional Pathway for FY 2023			
Technology Name	**Estimated Cases**	**FY 2023 NTAP Amount (65 % or 75 %)**	**Estimated Total FY 2023 Impact**
Carvykti™	241	$289,532.75	$69,777,392.75
DARZALEX FASPRO®	25	$5,159.41	$128,985.19
Hemolung Respiratory Assist System (RAS)	161	$6,500.00	$1,046,500.00
Livtencity™	129.5	$32,500.00	$4,208,750.00
Aggregate Estimated Total FY 2023 Impact			**$75,161,627.94**

c. Total Estimated Costs for NTAP in FY 2023

In the following table, we present summary estimates for all technologies approved for new technology add-on payments for FY 2023:

FY 2023 Estimates for New Technology Add-On Payments for FY 2023	
Category	**Estimated Total FY 2023 Impact**
Technologies Continuing New Technology Add-on Payments in FY 2023	$619,943,190.45
Alternative Pathway Applications	$88,454,632.50
Traditional Pathway Applications	$75,161,627.94
Aggregate Estimated Total FY 2023 Impact	**$783,559,450.89**

As discussed in section IV.D. of the preamble of this final rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals and any additional statutory adjustment (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care for all

hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this final rule, we are establishing the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2023 is $6,874,403,459.42. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 65.71 percent. For FY 2022, the amount available to be distributed for uncompensated care was $7,192,008,709.70 or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 68.57 percent. In addition, under the new supplemental payment for Indian Health Service (IHS) and Tribal Hospitals and Puerto Rico Hospitals, which we are establishing in this final rule, these hospitals will receive approximately $96.3 million in supplemental payments, as determined based on the difference between each hospital's FY 2022 UCP (reduced by negative 4.4 percent, which is the projected change between the FY 2023 total uncompensated care payment amount and the total uncompensated care payment amount for FY 2022) and its FY 2023 UCP as calculated using the methodology adopted in this final rule for FY 2023. For this final rule, the total uncompensated care payments and supplemental payments equal approximately $6.971 billion. For FY 2023, we are using 2 years of data on uncompensated care costs from Worksheet S–10 of the FY 2018 and 2019 cost reports to calculate Factor 3 for all DSH-eligible hospitals, including IHS/Tribal hospitals and Puerto Rico hospitals. For a complete discussion of the methodology for calculating Factor 3 for FY 2023 and the methodology for calculating the new supplemental payments, we refer readers to sections IV.D. and IV.E. of the preamble of this final rule.

To estimate the impact of the combined effect of the changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare uncompensated care payments along with the new supplemental payment for Puerto Rico hospitals and IHS and Tribal hospitals, which we are establishing using our authority under section 1886(d)(5)(I) of the Act, we compared total uncompensated care payments estimated in the FY 2022 IPPS/LTCH PPS final rule to the combined total of uncompensated care payments and supplemental payments estimated in this FY 2023 IPPS/LTCH PPS final rule. For FY 2022, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 68.57 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2022 IPPS/LTCH PPS final rule. For FY 2023, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments during FY 2023 absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 65.71 percent and multiplied by a Factor 3 calculated using the methodology described previously. For the supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals, we calculated the difference between the hospital's adjusted base year amount (as determined based on the hospital's FY 2022 uncompensated care payment) and the hospital's FY 2023 uncompensated care payment.

Our analysis included 2,368 hospitals that are projected to be eligible for DSH in FY 2023. It did not include hospitals that had terminated their participation in the Medicare program as of June 3, 2022, Maryland hospitals, new hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. The 26 hospitals that are anticipated to be participating in the Rural Community Hospital Demonstration Program were excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the non-surviving CCN was excluded from the analysis. The estimated impact of the changes in Factors 1, 2, and 3 on uncompensated care payments and of establishing the new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals across all hospitals projected to be eligible for DSH payments in FY 2023, by hospital characteristic, is presented in the following table:

Modeled Uncompensated Care Payments* and Supplemental Payments for Estimated FY 2023 DSHs by Hospital Type					
	Number of Estimated DSHs (1)	FY 2022 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2023 Uncompensated Care Payments and Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2022 - FY 2023 ($ in millions) (4)	Percent Change*** (5)
Total	**2,368**	**$7,192**	**$6,971**	**-$221**	**-3.08%**
By Geographic Location					
Urban Hospitals	1,920	6,789	6,592	-197	-2.90
Large Urban Areas	1,004	4,146	4,073	-73	-1.77
Other Urban Areas	916	2,643	2,519	-124	-4.69
Rural Hospitals	448	403	379	-24	-6.00
Bed Size (Urban)					
0 to 99 Beds	363	284	265	-19	-6.55
100 to 249 Beds	780	1,532	1,492	-39	-2.57
250+ Beds	777	4,974	4,835	-139	-2.80
Bed Size (Rural)					
0 to 99 Beds	346	219	206	-13	-5.81
100 to 249 Beds	90	136	127	-9	-6.81
250+ Beds	12	47	45	-2	-4.52
Urban by Region					
New England	87	186	175	-11	-5.91
Middle Atlantic	236	819	765	-54	-6.58
South Atlantic	315	800	762	-38	-4.76
East North Central	104	354	357	4	1.03
East South Central	322	1,759	1,713	-45	-2.58
West North Central	126	439	428	-10	-2.38
West South Central	236	1,434	1,401	-32	-2.26
Mountain	135	299	292	-7	-2.35
Pacific	316	607	611	3	0.52
Puerto Rico	43	93	87	-6	-6.24
Rural by Region					
New England	7	15	11	-3	-23.03
Middle Atlantic	21	12	12	0	-3.76
South Atlantic	66	43	43	-1	-1.81

Modeled Uncompensated Care Payments* and Supplemental Payments for Estimated FY 2023 DSHs by Hospital Type

	Number of Estimated DSHs (1)	FY 2022 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2023 Uncompensated Care Payments and Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2022 - FY 2023 ($ in millions) (4)	Percent Change*** (5)
East North Central	27	23	25	2	8.09
East South Central	77	117	107	-10	-8.74
West North Central	116	5	81	-4	-4.95
West South Central	105	88	81	-7	-8.51
Mountain	23	14	14	-1	-4.59
Pacific	6	5	6	1	24.45
By Payment Classification					
Urban Hospitals	1,457	4,482	4,372	-110	-2.46
Large Urban Areas	831	2,950	2,913	-37	-1.27
Other Urban Areas	626	1,532	1,459	-73	-4.76
Rural Hospitals	911	2,710	2,599	-111	-4.10
Teaching Status					
Nonteaching	1,320	1,961	1,906	-55	-2.82
Fewer than 100 residents	779	2,486	2,426	-60	-2.40
100 or more residents	269	2,746	2,639	-106	-3.88
Type of Ownership					
Voluntary	1,478	4,102	4,022	-80	-1.95
Proprietary	530	1,017	992	-24	-2.37
Government	360	2,073	1,956	-117	-5.65
Medicare Utilization Percent****					
0 to 25	694	3,434	3,334	-101	-2.94
25 to 50	1,553	3,685	3,566	-120	-3.25
50 to 65	111	70	70	0	-0.38
Greater than 65	9	2	2	0	-23.82
Medicaid Utilization Percent****					
0 to 25	1,378	$3,346	3,262	-84	-2.50
25 to 50	866	3,092	3,019	-73	-2.35
50 to 65	100	674	603	-71	-10.49
Greater than 65	24	81	86	5	6.67

Source: Dobson | DaVanzo analysis of 2018 and 2019 Hospital Cost Reports.

*Dollar uncompensated care payments calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, uncompensated care payments are estimated to be $7,192 million in FY 2022 and uncompensated care payments and supplemental payments are estimated to be $6,971 million in FY 2023.

** For IHS/Tribal hospitals and Puerto Rico hospitals, this impact table reflects the supplemental payments.

*** Percentage change is determined as the difference between Medicare uncompensated care payments and supplemental payments modeled for this FY 2023 IPPS/LTCH PPS final rule (column 3) and Medicare uncompensated care payments modeled for the FY 2022 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare uncompensated care payments modeled for the FY 2022 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.

****Hospitals with missing or unknown Medicare utilization or Medicaid utilization are not shown in the table.

The changes in projected FY 2023 uncompensated care payments and supplemental payments compared to the total uncompensated care payments in FY 2022 are driven by a decrease in Factor 1 and a decrease in Factor 2 and the establishment of a new supplemental payment for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals. Factor 1 has decreased from the FY 2022 final rule's Factor 1 of $10.489 billion to this final rule's Factor 1 of $10.461 billion, while the percent change in the percent of individuals who are uninsured (Factor 2) has decreased from 68.57 percent to 65.71 percent. In addition, we note that there is a slight increase in the number of projected DSHs to 2,368 at the time of the development for this final rule compared to the projected 2,365 DSHs in the FY 2022 IPPS/LTCH PPS correction notice (86 FR 58034). Based on the changes, the impact analysis found that, across all projected DSH eligible hospitals, FY 2023 uncompensated care payments and supplemental payments are estimated at approximately $6.971 billion, or a decrease of approximately 3.08 percent from FY 2022 uncompensated care payments (approximately $7.192 billion). While these changes will result in a net decrease in the total amount available to be distributed in uncompensated care payments and supplemental payments, the projected payment decreases vary by hospital type.

This redistribution of payments is caused by changes in Factor 3 and the establishment the new supplemental payment for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals. As seen in the previous table, a percent change of less than negative 3.08 percent indicates that hospitals within the specified category are projected to experience a larger decrease in payments, on average, compared to the universe of projected FY 2023 DSH hospitals. Conversely, a percent change greater than negative 3.08 percent indicates that a hospital type is projected to have a smaller decrease in payments or an increase compared to the overall average. The variation in the distribution of overall payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported on the Worksheet S–10 and used in the Factor 3 computation and whether the hospital is eligible to receive the new supplemental payment.

Rural hospitals, in general, are projected to experience larger decreases in uncompensated care payments and supplemental payments compared to their uncompensated care payments in FY 2022, than their urban counterparts. Overall, rural hospitals are projected to receive a 6.00 percent decrease in payments, which is a greater decrease than the overall hospital average, while urban hospitals are projected to receive a 2.90 percent decrease in payments, which is a slightly smaller decrease than the overall hospital average.

By bed size, larger rural hospitals are projected to receive the smallest decreases in uncompensated care payments and supplemental payments among rural hospitals. Rural hospitals with 250+ beds are projected to receive a 4.52 percent payment decrease, and rural hospitals with 100–249 beds are projected to receive a 6.81 percent decrease. Smaller rural hospitals with 0–99 beds are projected to receive a 5.81 percent payment decrease. Among urban hospitals, the smallest hospitals, those with 0–99 beds, are projected to receive a 6.55 percent decrease in payments, which is a greater decrease than the overall hospital average. In contrast, urban hospitals with 100–249 beds and those with 250+ beds are projected to receive decreases in payments of 2.57 and 2.80 percent, respectively, which are smaller decreases than the overall hospital average.

By region, rural hospitals are generally expected to receive larger than average decreases in uncompensated care payments and supplemental payments in most regions. The exceptions are rural hospitals in the South Atlantic Region, which are projected to receive a smaller than average decrease of 1.81 percent in payments and rural hospitals in the East North Central Region and the Pacific Region, which are projected to receive payment increases of 8.09 and 24.45 percent, respectively. Regionally, urban hospitals are projected to receive a more varied range of payment changes. Urban hospitals in the New England, Middle Atlantic, and South Atlantic Regions, as well as hospitals in Puerto Rico, are projected to receive larger than average decreases in payments. Urban hospitals in the East South Central, West North Central, West South Central, and Mountain Regions are projected to receive smaller than average decreases in payments. Urban hospitals in the East North Central and Pacific Regions are projected to receive increases in average payments of 1.03 percent and 0.52 percent, respectively.

By payment classification, although hospitals in urban payment areas overall are expected to receive a 2.46 percent decrease in uncompensated care payments and supplemental payments, hospitals in large urban payment areas are expected to see a decrease in payments of 1.27 percent, while hospitals in other urban payment areas are projected to receive the largest decrease of 4.76 percent. Hospitals in rural payment areas are expected to receive a decrease in payments of 4.10 percent.

Nonteaching hospitals are projected to receive a payment decrease of 2.82 percent, teaching hospitals with fewer than 100 residents are projected to receive a decrease of 2.40 percent, and teaching hospitals with 100+ residents have a projected payment decrease of 3.88 percent. Proprietary and voluntary hospitals are projected to receive smaller than average decreases of 2.37 and 1.95 percent respectively, while government hospitals are expected to receive a larger than average payment decrease of 5.65 percent. Hospitals with less than 25 percent Medicare utilization and hospitals with 50 to 65 percent Medicare utilization are projected to receive smaller than average payment decreases of 2.94 and 0.38 percent, respectively, while hospitals with 25–50 percent and hospitals with greater than 65 percent Medicare utilization are projected to receive larger than average payment decreases of 3.25 and 23.82 percent, respectively. All hospitals with less than 50 percent Medicaid utilization are projected to receive smaller decreases in uncompensated care payments and supplemental payments than the overall hospital average percent change, while hospitals with 50–65 percent Medicaid utilization are projected to receive larger than average decreases of 10.49 percent. Hospitals with greater than 65 percent Medicaid utilization are projected to receive an increase of 6.67 percent.

The previous impact table reflects the total combined uncompensated care payments and supplemental payments modeled for FY 2023 for IHS/Tribal and Puerto Rico hospitals. In FY 2023, IHS/Tribal hospitals' and Puerto Rico hospitals' aggregate uncompensated care payments are estimated to decrease by approximately $103 million while the aggregate supplemental payments to these hospitals are estimated to be approximately $96 million, a net decrease of approximately $7 million. This difference is primarily attributable to the change in the estimated amount available for uncompensated care payments in FY 2023 and estimated changes in DSH status. We refer readers to the discussion of the methodology for calculating the new supplemental payments in sections IV.E. of the preamble of this final rule. For the estimated impacts on individual IHS/Tribal hospitals and Puerto Rico hospitals, we refer readers to the IPPS Payment Impact File, which can be found on the FY 2023 IPPS final rule home page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We note that the amounts for this final rule differ from the proposed rule amounts primarily due to updated estimates of the amount available for uncompensated care payments for FY 2023.

3. Effects of Changes to Low-Volume Hospital Payment Adjustment Policy

In section V.C. of the preamble of this final rule, we discuss the expiration of the temporary changes to the low-volume hospital payment policy originally provided for by the Affordable Care Act and extended through FY 2022 by subsequent legislation. Effective for FY 2023 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. Based upon the best available data at this time, we estimate the expiration of the temporary changes to the low-volume hospital payment policy will decrease aggregate low-volume hospital payments by $437 million in FY 2023 as compared to FY 2022. These payment estimates were determined based on the estimated payments for the 632 providers that are expected to no longer qualify under the criteria that will apply in FY 2023, and were calculated using the same methodology used in developing the quantitative analyses of changes in payments per case discussed previously in section I.G. of this Appendix A.

4. Effects of Reductions Under the Hospital Readmissions Reduction Program for FY 2023

In section V.H of the preamble of this final rule, we discuss our policies for the FY 2023 Hospital Readmissions Reduction Program. This program requires a reduction to a hospital's base operating MS–DRG payment to account for excess readmissions of selected applicable conditions and procedures. The table and analysis in this final rule illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristics. In the proposed rule, for the purpose of modeling the estimated FY 2023 payment adjustment factors that account for the suppression of the pneumonia readmission measure, we used the data from the FY 2022 Hospital Readmissions Reduction Program for the five non-suppressed measures (acute myocardial infarction—AMI, heart failure—HF, chronic obstructive pulmonary disease—COPD, coronary artery bypass graft—CABG, and total hip arthroplasty/total knee arthroplasty—THA/TKA) and the FY 2022 Hospital IPPS Proposed Rule Impact File to analyze results by hospital characteristics. In this final rule, we are updating the estimated financial impact using the estimated payment adjustment factors from the FY 2023 Hospital Readmissions Reduction Program and the FY 2023 Hospital IPPS Proposed Rule Impact File to analyze results by hospital characteristics.

Hospitals are sorted into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed

care stays between July 1, 2018 and December 1, 2019 and July 1, 2020 through June 30, 2021 (that is, the data period used for the FY 2023 Hospital Readmissions Reduction Program). Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality. In this final rule, we are providing an updated estimate of the financial impact using the proportion of dually-eligible beneficiaries, ERRs, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2023 Hospital Readmissions Reduction Program applicable period. We note that for the FY 2023 applicable period, we will only be assessing data from July 1, 2018 through December 1, 2019 and from July 1, 2020 through June 30, 2021 due to the COVID–19 public health emergency (PHE) nationwide Extraordinary Circumstance Exception (ECE) which excluded data from January 1, 2020 through June 30, 2020 from the Hospital Readmissions Reduction Program calculations.[1169]

The results in the table include 2,849 non-Maryland hospitals eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between July 1, 2018 through December 1, 2019 and July 1, 2020 through June 30, 2021. The second column in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals).

The third column in the table indicates the percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 74.85 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 86.77 percent of eligible hospitals with fewer than 100 residents and 88.06 percent of eligible hospitals with 100 or more residents are expected to be penalized.

The fourth column in the table estimates the financial impact on hospitals by hospital characteristic. The table shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2020 through September 30, 2021 (FY 2021). For example, the penalty as a share of payments for non-teaching hospitals is 0.47 percent. This means that total penalties for all non-teaching hospitals are 0.47 percent of total payments for non-teaching hospitals. Measuring the financial impact on hospitals as a percentage of total base operating MS–DRG payments accounts for differences in the amount of base operating MS–DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

[1169] Although the FY 2023 performance period is July 1, 2018 through June 30, 2021, first and second quarter data from CY 2020 is excluded from program calculations due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for calculating MS–DRG payments will be adjusted to July 1, 2018 through December 1, 2019 and then July 1, 2020 through June 30, 2021. Taking into consideration the 30-day window to identify readmissions, the period for identifying index stays will be adjusted to July 1, 2018 through December 1, 2019 and July 1, 2020 through June 30, 2021.

Estimated Percentage of Hospitals Penalized and Penalty as Share of Payments for FY 2023 Hospital Readmissions Reduction Program by Hospital Characteristic				
Hospital Characteristic	**Number of Eligible Hospitals[a]**	**Number of Penalized Hospitals[b]**	**Percentage of Hospitals Penalized[c] (%)**	**Penalty as a Share of Payments[d] (%)**
All Hospitals	2,849	2,273	79.78	0.42
By Geographic Location (n=2,847)				
Urban hospitals	2,175	1,789	82.25	0.42
1-99 beds	492	320	65.04	0.48
100-199 beds	643	547	85.07	0.48
200-299 beds	403	344	85.36	0.45
300-399 beds	279	255	91.40	0.46
400-499 beds	121	109	90.08	0.42
500 or more beds	237	214	90.30	0.34
Rural hospitals	672	482	71.73	0.44
1-49 beds	300	180	60.00	0.35
50-99 beds	210	155	73.81	0.48
100-149 beds	85	74	87.06	0.41
150-199 beds	41	38	92.68	0.48
200 or more beds	36	35	97.22	0.44
By Teaching Status[e] (n=2,847)				
Non-teaching	1,702	1,274	74.85	0.47
Fewer than 100 residents	877	761	86.77	0.43
100 or more residents	268	236	88.06	0.35
By Ownership Type (n=2,846)				
Government	390	293	75.13	0.35
Proprietary	674	525	77.89	0.58
Voluntary	1,782	1,453	81.54	0.40
By Safety-net Status[f] (n=2,847)				
Safety-net hospitals	551	442	80.22	0.31
Non-safety-net hospitals	2,296	1,829	79.66	0.45
By Disproportionate Share Hospital (DSH) Patient Percentage[g] (n= 2,847)				
0-24	1,136	869	76.50	0.50
25-49	1,410	1,165	82.62	0.39
50-64	181	149	82.32	0.31
65 and over	120	88	73.33	0.22
By Medicare Cost Report (MCR) Percentage[h,i] (n= 2,842)				
0-24	533	424	79.55	0.33
25-49	2,005	1,618	80.70	0.43
50-64	277	211	76.17	0.62
65 and over	27	15	55.56	0.48
By Region (n=2,849)				
New England	124	110	88.71	0.62
Middle Atlantic	321	278	86.60	0.43
East North Central	462	368	79.65	0.46
West North Central	232	168	72.41	0.22
South Atlantic	481	417	86.69	0.49
East South Central	246	202	82.11	0.47
West South Central	430	337	78.37	0.39
Mountain	210	134	63.81	0.36
Pacific	343	259	75.51	0.29

Source: The table results are based on the estimated FY 2023 payment adjustment factors of open, non-Maryland, subsection (d) hospitals. The estimated FY 2023 payment adjustment factors are based on discharges between July 1, 2018 to December 1, 2019 and July 1, 2020 to June 30, 2021 (the FY 2023 Hospital Readmissions Reduction Program performance period). Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals and hospitals that are not open as of the

October 2022 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are sorted into quintiles based on the proportion of Medicare FFS and managed care dual-eligible stays for the multi-year performance period. Hospital characteristics are from the FY 2023 Hospital IPPS proposed rule Impact File.

As discussed in the FY 2022 IPPS/LTCH PPS final rule, CMS will not use claims data representing quarter (Q)1 and Q2 2020 in its calculations for the Hospital Readmissions Reduction Program (86 FR 45260 - 45261). The readmission measures used in the Hospital Readmissions Reduction Program identify readmissions within 30 days of each index stay; therefore, the performance period for the Hospital Readmissions Reduction Program will also not use claims data representing the 30 days before January 1, 2020. The FY 2023 performance period for HRRP is July 1, 2018, to December 1, 2019, and July 1, 2020, to June 30, 2021, so that no claims from Q1 and Q2 2020 are used in the measure or program calculations. As finalized in the FY 2022 IPPS/LTCH PPS final rule, the pneumonia readmission measure is suppressed from FY 2023 Hospital Readmissions Reduction Program payment reduction calculations due to the COVID-19 PHE's substantial impact on this measure (86 FR 45254-45256). The pneumonia measure results do not contribute to FY 2023 Hospital Readmissions Reduction Program calculations.

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating MS-DRG payments for all those hospitals. MedPAR data from October 1, 2020 through September 31, 2021 (FY 2021) are used to calculate the total base operating MS-DRG payments.

[e] The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for geographic location, teaching status, safety-net status, and DSH patient percentage (n=2,847; missing=2 for each), ownership type (n=2,846; missing=3), or MCR percentage (n=2,842; missing=7).

[f] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[g] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[h] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[i] MCR percent is the percentage of total inpatient stays from Medicare patients.

5. Effects of Changes Under the FY 2023 Hospital Value-Based Purchasing (VBP) Program

In section V.I. of the preamble of this final rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. We are finalizing our proposals to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey and five Healthcare-Associated Infection (HAI) measures, as well as to change the scoring and payment methodologies for the FY 2023 program year, such that hospitals would receive a value-based incentive payment percentage that results in a value-based incentive payment amount that is equal to the applicable percentage (2 percent). Specifically, we are finalizing our proposal such that we would calculate the measure rates for all of the measures we have selected for the FY 2023 program year, but we would not generate achievement or improvement points for any of the measures we are finalizing for suppression. Additionally, we are finalizing our proposal to not award domain scores for the Person and Community Engagement and Safety domains. We are also not awarding hospitals a Total Performance Score (TPS), and will instead award hospitals a payment incentive multiplier that results in a value-based incentive payment amount that is equal to the amount withheld for the fiscal year (2 percent). That is, each hospital will receive a 2-percent reduction to its base operating DRG payment amount for each FY 2023 discharge and will then receive a value-based incentive payment percentage that will result in a value-based incentive payment amount that is equal to the 2 percent withheld. Because we are finalizing these proposals, the impact for every hospital under the Hospital VBP Program will be a net percentage payment adjustment of zero.

In the FY 2023 IPPS/LTCH PPS proposed rule, we provided the estimated impact of the FY 2023 program because those impacts would apply if the proposals discussed previously were not finalized. However, because we are finalizing the policies as proposed, all adjustment factors for all hospitals will reflect a net-neutral payment adjustment for hospitals in accordance with the finalized FY 2023 special scoring policy at § 412.168.

6. Effects of Changes Under the HAC Reduction Program for FY 2023

In the FY 2023 IPPS/LTCH PPS proposed rule, we presented the estimated impact of the FY 2023 Hospital-Acquired Condition (HAC) Reduction Program on hospitals by hospital characteristics in the following table. The table in this section presents the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores by hospital characteristic and includes 3,119 non-Maryland hospitals that participate in the HAC Reduction Program. The first column presents a breakdown of each characteristic and the second column indicates the number of hospitals for the respective characteristic. The third column in the table indicates the number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. The fourth column in the table indicates the proportion of hospitals for each characteristic that would be in the worst performing quartile of Total HAC Scores.

In section V.J.2.b.(2). of this FY 2023 IPPS/LTCH PPS final rule, we are finalizing our proposal to suppress all six measures from the HAC Reduction Program, calculate only measure results for the HAI measures for the FY 2023 program, and not calculate measure scores or Total HAC Scores. Additionally, we are not finalizing our proposal to not calculate measure results for the CMS PSI 90 measure and thus will be calculating measure results for purposes of public reporting for the FY 2023 program.

Accordingly, since we are finalizing the measure suppression proposal, no hospitals will receive a payment reduction in the FY 2023 HAC Reduction Program.[1170] In Table 1, we present the estimated impact of the FY 2023 HAC Reduction Program on hospitals by hospital characteristic for the finalized proposal in section V.J.2.b.(2). whereby FY 2023 HAC Reduction Program measure scores and Total HAC scores are not calculated. Therefore, Table 1 illustrates the number of hospitals participating in the FY 2023 HAC Reduction Program by hospital characteristic; however, the remaining two columns reflect values of zero because no hospital would be in the worst-performing quartile.

[1170] Based on finalizing our suppression proposals, we anticipate reduced savings to the Medicare trust fund that is otherwise estimated at approximately $350 million.

Table 1- Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2023 HAC Reduction Program (by Hospital Characteristic)- Finalizing the Proposal in Section V.J.2.b.(2).			
Hospital Characteristic	**Number of Hospitals**	**Number of Hospitals in the Worst-performing Quartile[a]**	**Percent of Hospitals in the Worst-performing Quartile[b]**
Total[c]	3,119	0	0
By Geographic Location (n = 3,089)[d]			
Urban hospitals	**2,355**	**0**	**0**
1-99 beds	622	0	0
100-199 beds	674	0	0
200-299 beds	416	0	0
300-399 beds	283	0	0
400-499 beds	122	0	0
500 or more beds	238	0	0
Rural hospitals	**734**	**0**	**0**
1-49 beds	358	0	0
50-99 beds	213	0	0
100-149 beds	86	0	0
150-199 beds	41	0	0
200 or more beds	36	0	0
By Safety-Net Status[e] (n = 3,089)			
Non-safety net	2,464	0	0
Safety-net	625	0	0
By DSH Percent[f] (n = 3,089)			
0-24	1,266	0	0
25-49	1,464	0	0
50-64	201	0	0
65 and over	158	0	0
By Teaching Status[g] (n =3,089)			
Non-teaching	1,907	0	0
Fewer than 100 residents	912	0	0
100 or more residents	270	0	0
By Ownership[h] (n = 3,088)			
Voluntary	1,874	0	0
Proprietary	754	0	0
Government	460	0	0
By MCR Percent[i] (n = 3,044)			
0-24	643	0	0
25-49	2,070	0	0
50-64	294	0	0
65 and over	37	0	0
By Region[j] (n= 3,099)			
New England	130	0	0
Mid-Atlantic	333	0	0
South Atlantic	507	0	0
East North Central	483	0	0
East South Central	282	0	0
West North Central	246	0	0
West South Central	500	0	0
Mountain	235	0	0
Pacific	383	0	0

Source: FY 2023 HAC Reduction Program final rule results are based on CDC NHSN HAI results from January 1, 2021 through December 31, 2021. Hospital Characteristics are based on the FY 2023 Proposed Rule Impact File.

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2023 Total HAC Score (N = 3,119). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH percent, and teaching status (n = 3,089).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for Ownership (n = 3,088).

[i] Not all hospitals had data for MCR percent (n = 3,044).

[j] Not all hospitals had data for Region (n = 3,099).

7. Effects of the Changes to IME and Direct GME Payments

a. Change to Direct GME Calculation in Response to Decision in **Milton S. Hershey Medical Center et al** v. **Azar II**

As discussed in section V.F.2. of the preamble of this final rule, we are implementing a modified direct GME payment policy for all teaching hospitals. Specifically, effective for cost reporting periods beginning on or after October 1, 2001, for cost reports that are reopenable or open, if the hospital's unweighted number of FTE residents exceeds the FTE cap, and the number of weighted FTE residents also exceeds that FTE cap, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the FTE cap. If the number of weighted FTE residents does not exceed that FTE cap, then the allowable weighted FTE count for direct GME payment is the actual weighted FTE count. We have estimated the impact of this change for FY 2023 to be $170 million.

b. Effects of Allowing Medicare GME Affiliation Agreements Within Certain Rural Track FTE Limitations

In section V.F.4. of the preamble of this final rule, we are finalizing a policy to allow urban and rural hospitals that participate in the same separately accredited 1–2 family medicine rural track program and have rural track FTE limitations to enter into ''rural track Medicare GME affiliation agreements'' in order to share those cap slots, and facilitate the cross-training of residents. In addition, the final policy only allows urban and rural hospitals to participate in rural track Medicare GME affiliated groups if they have rural track FTE limitations in place prior to October 1, 2022. Under the final policy, eligible urban and rural hospitals may enter into rural track Medicare GME affiliation agreements effective with the July 1, 2023, academic year. Because no newly funded cap slots will be created, only existing funded cap slots would be shared between the participating affiliated hospitals, there is no financial impact to this provision.

8. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2022

In section V.K. of the preamble of this final rule for FY 2023, we discussed our implementation and budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, by section 15003 of Public Law 114–255, and most recently, by section 128 of Public Law 116–260, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 128 of Public Law 116–260 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 15-year extension period (that is, for an additional 5 years beyond the previous extension period). In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019.

Section 410A(c)(2) of Public Law 108–173 requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality). We propose to adopt the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration, and then adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

For this final rule, the resulting amount applicable to FY 2023 is $72,449,896, which we are including in the budget neutrality offset adjustment for FY 2023. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and currently finalized update factors for cost and payment.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the final IPPS rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2016 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 128 of Public Law 116–260, we will continue this general procedure. At the time of the FY 2023 proposed rule, all of the finalized cost reports are available for the 17 hospitals that completed cost report periods beginning in FY 2017 under the demonstration payment methodology; these cost reports show the actual costs of the demonstration for this fiscal year to be $35,989,928. We note that the FY 2017 IPPS final rule included no budget neutrality offset amount for that fiscal year. The final rule for FY 2017 preceded the re-authorization of the demonstration under the Cures Act. Anticipating that the demonstration would end in 2016, we projected no demonstration cost estimate for the upcoming fiscal year, FY 2017, while we stated that we would continue to reconcile actual costs when all finalized cost reports for previous fiscal years under the demonstration became available

(81 FR 57037). Thus, keeping with past practice, for this final rule we are including the actual costs of the demonstration as determined from finalized cost reports for FY 2017 within the budget neutrality offset amount for this upcoming fiscal year.

Therefore, for this FY 2023 IPPS/LTCH PPS final rule, the budget neutrality offset amount for FY 2023 is based on the sum of two amounts:

- The amount representing the difference applicable to FY 2023 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 26 hospitals participating in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $72,449,896.
- The amount by which the actual costs of the demonstration in FY 2017 (as shown by finalized cost reports from that fiscal year) differ from the amount determined for FY 2017. Since no budget neutrality offset was conducted in FY 2017, the amount of this difference is the actual cost amount for FY 2017 $35,989,928.

We are thus subtracting the sum of these amounts ($108,439,824) from the national IPPS rates for FY 2023.

9. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VIIB.2. of the preamble of this final rule we discuss the implementation of the FCHIP Demonstration, which allows eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four States. Section 123 of Public Law 110–275 initially required a 3-year period of performance. The FCHIP Demonstration began on August 1, 2016, and concluded on July 31, 2019 (referred to in this section as the ''initial period''). Section 129 of the Consolidated Appropriations Act (Pub. L. 116–159) extended the FCHIP Demonstration by 5 years (referred to in this section as the ''extension period'' of the demonstration). The FCHIP Demonstration resumed on January 1, 2022 and CAHs participating in the demonstration project during the extension period shall begin such participation in the cost reporting year that begins on or after January 1. Budget neutrality estimates for the demonstration described in the preamble of this final rule are based on the demonstration extension period.

As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS waived certain Medicare rules for CAHs participating in the demonstration initial period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. As we explained in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), 10 CAHs were selected for participation in the demonstration initial period. Section 129 of Public Law 116–159, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, six elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing the three intervention services. In the FY 2022 IPPS/LTCH PPS final rule, CMS concluded that the initial period of the FCHIP Demonstration had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration. In addition, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), we finalized a policy to address the budget neutrality requirement for the demonstration initial period. We also discussed this policy in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 through 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58996).

As explained in the FY 2022 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration initial period of performance in the FY 2022 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

For this final rule, we are adopting the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period is not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

Under the policy finalized in the FY 2022 IPPS/LTCH PPS final rule, we adopted the policy finalized in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration initial period was found not to have been budget neutral, any excess costs would be recouped over a period of 3 cost reporting years. In the FY 2023 IPPS/LTCH PPS proposed rule, we sought public comment on the proposal, as we proposed to revise an aspect of the policy finalized in the FY 2022 IPPS/LTCH PPS final rule. Our new proposed policy is in the event the demonstration extension period is found not to have been budget neutral, any excess costs would be recouped within 1 fiscal year. We believe our new proposed policy is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data and/or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period. As explained in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration initial period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, our policy is to comply with the budget neutrality requirement finalized in the FY 2022 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period. We stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. As we explained in the FY 2022 IPPS/LTCH PPS final rule, we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. Therefore, for the proposed rule, we proposed to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to ensure budget neutrality for the extension period. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and

analytical approach to ensure that the full impact of the demonstration is appropriately captured. Therefore, we did not propose to apply a budget neutrality payment offset to payments to CAHs in FY 2023. This policy will have no impact for any national payment system for FY 2023.

10. Effects of Codification of the Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans

In section X.A. of the preamble of this final rule, we set forth our provisions to codify the costs incurred for qualified and non-qualified deferred compensation plans. We do not believe that there are any costs associated with the codification of this policy.

11. Effects of Condition of Participation (CoP) Requirements for Hospitals and CAHs To Continue Reporting Data for COVID–19 and Influenza After the PHE Ends as Determined by the Secretary

Section X.B. of the preamble of this final rule revises the hospital and CAH infection prevention and control CoP requirements to require hospitals and CAHs, after the conclusion of the current COVID–19 PHE, to continue COVID–19 and seasonal influenza related reporting. The revisions will continue to apply upon conclusion of the COVID–19 PHE and will continue until April 30, 2024, unless the Secretary establishes an earlier ending date. Reporting frequency and requirements will be communicated to hospitals, stakeholders, and the public following a model similar to that which we used to inform regulated entities at the beginning of the COVID–19 PHE (see *QSO-21-03-Hospitals/CAHs at https://www.cms.gov/files/document/qso-21-03-hospitalscahs.pdf-0*). As discussed in section XII.B. of the preamble of this final rule, Collection of Information Requirements, we expect a burden increase of $38,204,400 or approximately $6,162 per facility annually for weekly reporting. We note that efforts are underway to automate hospital and CAH reporting that have the potential to significantly decrease reporting burden and improve reliability.

Comment: Commenters noted that the data being collected for automating this type of reporting would not generally come from a single system, noting that for example, clinical data might come from the EHR, bed capacity from a bed management system, PPE from inventory systems, and medication and vaccination inventory from pharmacy information. These commenters noted that resources will vary among facilities and that some might use a combination of manual and automated solutions because they may not have (or need) all of these different systems. Commenters also emphasized the importance of IT staff in the deployment and maintenance of such systems. A commenter noted that estimates are available for the initial costs for the development of various interfaces, ranging from $3,000 to $25,000 depending on complexity and features, however did not cite any specific resources. In total, the commenter indicated that the cost for the development of the initial software to support long-term data collection could be as much as $250,000 depending on the specific needs of the facility and that maintenance costs to support the infrastructure could be between 10 and 25 percent of the initial software cost, totaling around $300,000 for a 2-year period. The commenter noted that some of these costs may be offset by the ability of the IT staff to repurpose existing automated solutions, but noted this may only be feasible in larger hospitals with more advanced IT staff and capabilities. Lastly, the commenter indicated that many CAHs have a much lower capacity to support IT innovation and are unable to fund extensive IT departments. Therefore, the costs for this type of innovation are likely to be much higher.

Response: We acknowledge that there are uncertainties in planning for future emergencies, and we understand that there are lots of incentives and pathways to consider with regard to preparedness. These comments are helpful in understanding the actions necessary and effort involved in tracking and investing in infrastructure to be prepared to timely and accurately report in the event of a future PHE declaration. We will consider this feedback as we continue to assess the best way to align and incentivize preparedness, while also reducing ongoing burden and costs on regulated entities, and ensuring flexibility to quickly respond to emergencies.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented in this section of the final rule, we used data from the March 2022 update of the FY 2021 MedPAR file and the March 2022 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2022 update of the most recently available hospital cost report data to categorize hospitals. Our analysis has several qualifications and uses the best data available, as described later in this section of the final rule.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the March 2022 update of the FY 2021 MedPAR file, we simulated payments under the capital IPPS for FY 2022 and the payments for FY 2023 for a comparison of total payments per case. Short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2023 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the geographic adjustment factor (GAF) and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this final rule, the update to the capital Federal rate is 2.5 percent for FY 2023.
- In addition to the FY 2023 update factor, the FY 2023 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 1.0012, a budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy of 0.9972, and a outlier adjustment factor of 0.9448.

2. Results

We used the payment simulation model previously described in section I.I. of Appendix A of this final rule to estimate the potential impact of the changes for FY 2023 on total capital payments per case, using a universe of 3,142 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the March 2022 update of the FY 2021 MedPAR file, the March 2022 update to the PSF, and the most recent available cost report data from the March 2022 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2022 and estimated total payments per case for FY 2023 based on the FY 2023 payment policies. Column 2 shows estimates of payments per case under our model for FY 2022. Column 3 shows estimates of payments per case under our model for FY 2023. Column 4 shows the total percentage change in payments from FY 2022 to FY 2023. The change represented in Column 4 includes the 2.50 percent update to the capital Federal rate and other changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2023 are expected to increase 0.6 percent compared to capital payments per case in FY 2022. This expected increase is primarily due to the 2.50 percent update to the capital Federal rate for FY 2023 being partially offset by an expected decrease in capital outlier payments. As discussed in section III.A.2. of the Addendum to this final rule, we estimate for FY 2023 that outlier payments for capital-

related PPS payments would equal 5.52 percent of inpatient capital-related payments. Although in the FY 2022 IPPS/LTCH PPS final rule we estimated for FY 2022 that outlier payments for capital-related PPS payments would equal 5.29 percent of inpatient capital related payments, our payment simulation model for this final rule shows that for FY 2022, estimated outlier payments for capital-related PPS payments are approximately 7.16 percent of inpatient capital-related payments. This difference in our estimate of FY 2022 outlier payments compared to our estimate of FY 2023 outlier payments is reflected in the average change in capital payments per case in FY 2023 as compared to FY 2022. Other factors that contribute to the expected change in average capital payments per case in FY 2023 as compared to FY 2022 include changes in capital DSH payments for hospitals that reclassify from urban to rural under § 412.103. In general, regional variations in estimated capital payments per case in FY 2023 as compared to capital payments per case in FY 2022 are primarily due to the changes in GAFs, and are generally consistent with the projected changes in payments due to changes in the wage index (and policies affecting the wage index), as shown in Table I in section I.G. of this Appendix A.

The net impact of these changes is an estimated 0.6 percent increase in capital payments per case from FY 2022 to FY 2023 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in both urban and rural classifications will experience an increase in capital IPPS payments per case in FY 2023 as compared to FY 2022. Capital IPPS payments per case will increase by an estimated 0.5 percent for hospitals in urban areas while payments to hospitals in rural areas will increase by 0.4 percent in FY 2022 to FY 2023.

The comparisons by region show that the change in capital payments per case from FY 2022 to FY 2023 for urban areas range from a 0.1 percent increase for the New England region to a 1.6 percent increase for the Mountain region. Meanwhile, the change in capital payments per case from FY 2022 to FY 2023 for rural areas range from a 0.7 percent decrease for the Mountain rural region to a 1.2 percent increase for the East South Central rural region. These regional differences are primarily due to the changes in the GAFs and estimated changes in outlier and DSH payments.

The comparison by hospital type of ownership (Voluntary, Proprietary, and Government) shows that proprietary hospitals are expected to experience the highest increase in capital payments per case from FY 2022 to FY 2023 of 0.9 percent. Meanwhile, government hospitals and voluntary hospitals are expected to experience an increase in capital payments per case from FY 2022 to FY 2023 of 0.6 percent and 0.5 percent, respectively.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2023. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this final rule for FY 2023, we show the average capital payments per case for reclassified hospitals for FY 2023. Urban reclassified hospitals are expected to experience an increase in capital payments of 0.3 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 0.7 percent. The lower expected increase in payments for urban reclassified hospitals compared to urban nonreclassified hospitals is primarily due to estimated decreases in capital DSH payments to urban reclassified hospitals caused by the number of hospitals that reclassify from urban to rural under § 412.103. Rural reclassified hospitals are expected to experience an increase in capital payments of 0.9 percent; rural nonreclassified hospitals are expected to experience a decrease in capital payments of 0.3 percent.

TABLE III.-- COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2022 PAYMENTS COMPARED TO FY 2023 PAYMENTS]

	Number of Hospitals	Average FY 2022 Payments/Case	Average FY 2023 Payments/Case	Change
All Hospitals	3,142	1,086	1,092	0.6
By Geographic Location:				
Urban hospitals	2,420	1,119	1,125	0.5
Rural hospitals	722	764	767	0.4
Bed Size (Urban):				
0-99 beds	653	883	884	0.1
100-199 beds	700	941	949	0.9
200-299 beds	411	1,035	1,043	0.8
300-499 beds	409	1,105	1,112	0.6
500 or more beds	245	1,326	1,329	0.2
Bed Size (Rural):				
0-49 beds	358	656	655	-0.2
50-99 beds	201	731	734	0.4
100-149 beds	84	742	750	1.1
150-199 beds	46	858	857	-0.1
200 or more beds	33	876	885	1.0
Urban by Region:				
New England	107	1,196	1,197	0.1
Middle Atlantic	295	1,253	1,259	0.5
East North Central	373	1,052	1,058	0.6
West North Central	156	1,070	1,077	0.7
South Atlantic	402	982	986	0.4
East South Central	140	945	951	0.6
West South Central	362	1,031	1,035	0.4
Mountain	176	1,115	1,133	1.6
Pacific	359	1,455	1,461	0.4
Puerto Rico	50	633	642	1.4
Rural by Region:				
New England	19	1,032	1,031	-0.1
Middle Atlantic	49	725	733	1.1
East North Central	113	753	755	0.3
West North Central	86	783	782	-0.1
South Atlantic	109	715	722	1.0
East South Central	141	723	732	1.2
West South Central	134	713	713	0.0
Mountain	47	857	851	-0.7
Pacific	24	977	977	0.0
By Payment Classification:				
Urban hospitals	1,861	1,080	1,087	0.6
Rural areas	1,281	1,094	1,098	0.4
Teaching Status:				
Nonteaching	1,939	904	909	0.6
Fewer than 100 residents	929	1,025	1,032	0.7
100 or more residents	274	1,471	1,476	0.3
Urban DSH:				
Non-DSH	369	970	973	0.3

	Number of Hospitals	Average FY 2022 Payments/Case	Average FY 2023 Payments/Case	Change
100 or more beds	1,129	1,112	1,121	0.8
Less than 100 beds	363	821	824	0.4
Rural DSH:				
Non-DSH	105	1,012	1,019	0.7
SCH	264	793	788	-0.6
RRC	674	1,147	1,150	0.3
100 or more beds	22	918	918	0.0
Less than 100 beds	216	647	653	0.9
Urban teaching and DSH:				
Both teaching and DSH	663	1,175	1,184	0.8
Teaching and no DSH	60	1,044	1,050	0.6
No teaching and DSH	829	958	965	0.7
No teaching and no DSH	309	932	934	0.2
Special Hospital Types:				
RRC	148	878	885	0.8
RRC with section 401 Rural Reclassification	470	1,215	1,218	0.2
SCH	256	745	744	-0.1
SCH with section 401 Rural Reclassification	47	906	895	-1.2
SCH and RRC	122	844	848	0.5
SCH and RRC with section 401 Rural Reclassification	39	1,005	1,017	1.2
Type of Ownership:				
Voluntary	1,915	1,090	1,095	0.5
Proprietary	789	1,000	1,009	0.9
Government	438	1,177	1,184	0.6
Medicare Utilization as a Percent of Inpatient Days:				
0-25	790	1,220	1,228	0.7
25-50	2,072	1,061	1,065	0.4
50-65	225	883	893	1.1
Over 65	30	690	690	0.0
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	2,082	1,006	1,010	0.4
25-50	942	1,220	1,228	0.7
50-65	94	1,447	1,457	0.7
Over 65	24	1,523	1,564	2.7
Hospitals with 5% or more of cases that reported experiencing homelessness	45	1,379	1,404	1.8
FY 2023 Reclassifications:				
All Reclassified Hospitals	1,004	1,113	1,118	0.4
Non-Reclassified Hospitals	2,138	1,064	1,070	0.6
Urban Hospitals Reclassified	840	1,149	1,153	0.3
Urban Non-Reclassified Hospitals	1,594	1,090	1,098	0.7
Rural Hospitals Reclassified Full Year	282	781	788	0.9
Rural Non-Reclassified Hospitals Full Year	426	741	739	-0.3
All section 401 Rural Reclassified Hospitals	615	1,175	1,178	0.3
Other Reclassified Hospitals (section 1886(d)(8)(B))	56	754	758	0.5

J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this final rule and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2023. In the preamble of this final rule, we specify the statutory authority for the provisions that are presented, identify the policies for FY 2023, and present rationales for our provisions as well as alternatives that were considered. In this section of Appendix A to this final rule, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 339 LTCHs included in this impact analysis. We note that, although there are currently approximately 346 LTCHs, for purposes of this impact analysis, we

excluded the data of all-inclusive rate providers consistent with the development of the FY 2023 MS–LTC–DRG relative weights (discussed in section VII.B.3.c. of the preamble of this final rule). Moreover, in the claims data used for this final rule, two of these 339 LTCHs only have claims for site neutral payment rate cases and, therefore, do not affect our impact analysis for LTCH PPS standard Federal payment rate cases.

In the impact analysis, we used the payment rate, factors, and policies presented in this final rule, the 3.8 percent annual update to the LTCH PPS standard Federal payment rate, the update to the MS–LTC–DRG classifications and relative weights, the update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2023.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2). In addition, there are two separate high cost outlier targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. We note that section 3711(b)(2) of the CARES Act has provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period. At the time of development of this final rule, the COVID–19 PHE is still in effect. Therefore, all LTCH PPS cases up to this point in FY 2022 have been paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. Since the expiration date of the COVID–19 PHE is not yet known, for purposes of this impact analysis, estimates of total LTCH PPS payments for site neutral payment rate cases in FYs 2022 and 2023 were calculated using the site neutral payment rate determined under § 412.522(c) and the provisions of the CARES Act were not considered.

Based on the best available data for the 339 LTCHs in our database that were considered in the analyses used for this final rule, we estimate that overall LTCH PPS payments in FY 2023 will increase by approximately 2.4 percent (or approximately $71 million) based on the rates and factors presented in section VII. of the preamble and section V. of the Addendum to this final rule.

Based on the FY 2021 LTCH cases that were used for the analysis in this final rule, approximately 28 percent of those cases were classified as site neutral payment rate cases (that is, 28 percent of LTCH cases did not meet the statutory patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2023 will not change significantly from the most recent historical data. We estimate IPPS comparable per diem amounts using the prior year's IPPS rates and factors, updated to reflect estimated changes to the IPPS rates and payments finalized for FY 2023. Taking this into account along with other changes that will apply to the site neutral payment rate cases in FY 2023, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will increase by approximately 2.8 percent (or approximately $9 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the finalized updates to the IPPS rates and payments reflected in our estimate of the IPPS comparable per diem amount, as well as an estimated increase in costs for these cases determined using the charge and CCR adjustment factors described in section V.D.3.b. of the Addendum to this final rule. We noted, we estimate payments to site neutral payment rate cases in FY 2023 will represent approximately 11 percent of estimated aggregate FY 2023 LTCH PPS payments.

Based on the FY 2021 LTCH cases that were used for the analysis in this final rule, approximately 72 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2023, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2023 will increase approximately 2.3 percent (or approximately $61 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2023 is primarily due to the 3.8 percent annual update to the LTCH PPS standard Federal payment rate for FY 2023 and the projected 1.2 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, which is discussed later in this section of the final rule.

Based on the 339 LTCHs that were represented in the FY 2021 LTCH cases that were used for the analyses in this final rule presented in this Appendix, we estimate that aggregate FY 2022 LTCH PPS payments will be approximately $2.985 billion, as compared to estimated aggregate FY 2023 LTCH PPS payments of approximately $3.056 billion, resulting in an estimated overall increase in LTCH PPS payments of approximately $71 million. We note that the estimated $71 million increase in LTCH PPS payments in FY 2023 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the policies in this final rule.

The LTCH PPS standard Federal payment rate for FY 2022 is $44,713.67. For FY 2023, we are establishing an LTCH PPS standard Federal payment rate of $46,432.77 which reflects the 3.8 percent annual update to the LTCH PPS standard Federal payment rate and the budget neutrality factor for updates to the area wage level adjustment of 1.0004304 (discussed in section V.B.6. of the Addendum to this final rule). For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $45,538.11. This LTCH PPS standard Federal payment rate reflects the updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP.

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the annual update of 3.8 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 3.6 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023, on average, for all LTCHs (Column 6). The estimated increase of 3.6 percent shown in Column 6 of Table IV also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. For most hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases also rounds to approximately 3.6 percent.

For FY 2023, we are updating the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2019 which is the same data used for the FY 2023 IPPS wage index). In addition, we are establishing a labor-related share of 68.0 percent for FY 2023, based on the most recent available data (IGI's second quarter 2022 forecast) on the relative importance of the labor-related share of operating and capital costs of the 2017-based LTCH market basket. We also applying an area wage level budget neutrality factor of 1.0004304 to ensure that the changes to the area wage level adjustment will not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

For LTCH PPS standard Federal payment rate cases, we currently estimate high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments will decrease from FY 2022 to FY 2023. Based on the FY 2021 LTCH cases that were used for the analyses in this final rule, we estimate that the FY 2022 high cost outlier threshold of $33,015 (as established in the FY 2022 IPPS/LTCH PPS final rule) will result in estimated high cost outlier payments for LTCH PPS standard Federal payment rate cases in FY 2022 that are projected to exceed the 7.975 percent target. Specifically, we currently estimate that high cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 9.15 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2022. Combined with our estimate that FY 2023 high cost outlier payments for LTCH PPS standard Federal payment rate cases will be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2023, this will result in an estimated decrease in high cost

outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments of approximately 1.2 percent between FY 2022 and FY 2023. We note that, in calculating these estimated high cost outlier payments, we inflated charges reported on the FY 2021 claims by the charge inflation factor in section V.D.3.b. of the Addendum to this final rule. We also note that, in calculating these estimated high cost outlier payments, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our finalized methodology described in section V.D.3.b. of the Addendum to this final rule.

Table IV shows the estimated impact of the payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2023 by comparing estimated FY 2022 LTCH PPS payments to estimated FY 2023 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.3. of this Appendix.

Comment: We received comments expressing concern about the 0.7 percent increase in payments to LTCH PPS standard Federal payment rate cases that we projected in the proposed rule. Many commenters stated that this projected increase was insufficient and failed to recognize the impact of increases in healthcare delivery costs on LTCHs. A commenter stated that the inadequacy of Medicare payments would continue to challenge the financial viability of LTCHs and their ability to provide care to Medicare and other patients. Another commenter stated that this projected increase is insufficient and would not allow LTCHs to compete for resources needed to care for patients.

Response: We appreciate commenters' concerns about the proposed 0.7 percent increase in payments to LTCH PPS standard Federal payment rate cases. Based on the finalized payment rates and factors in this final rule, we now project a 2.3 percent increase in payments to LTCH PPS standard Federal payment rate cases for FY 2023. This change in projected payments is primarily being driven by the annual update factor of 3.8 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 4.1 percent less the productivity adjustment of 0.3 percentage point) which is 1.1 percent higher than the proposed annual update factor. As discussed in section VIII.C.2. of the preamble to this final rule, we believe this LTCH market basket increase appropriately reflects the input price growth that LTCHs will incur while providing medical services in FY 2023. We note that the final FY 2023 LTCH market basket growth rate of 4.1 percent is the highest market basket update implemented in an IPPS/LTCH final rule since RY 2004.

Comment: Multiple commenters expressed concern about the immediate, full implementation of the site neutral payment policy following the end of the PHE waiver. Several of these commenters stated their belief that cases paid at the site neutral payment rate will continue to be underpaid as those cases, according to commenters, have on average higher levels of clinical complexity and costs that significantly exceed IPPS-level payment. Some commenters requested that CMS implement transition policies once the PHE ends that would phase in the full implementation of the site neutral payment policy, believing such a transition period would help prevent disruptions to LTCHs' operations. A commenter recommended that CMS pay site neutral cases a blended site neutral and standard Federal payment rate during this transition period.

Response: We acknowledge commenters' concerns about the costs of treating site neutral cases, however, as noted by some commenters and discussed previously, the site neutral payment rate is a statutory requirement and the statutory waiver of the site neutral payment is only authorized for the duration of the COVID–19 PHE. We did not propose any transition policies that would take effect following the end of the PHE waiver. We note that on January 22, 2021, then-acting Secretary of HHS, Norris Cochran, sent a letter to governors announcing that when a decision is made to terminate the public health emergency or let it expire, HHS will provide states with 60 days' notice prior to termination.[1171] Therefore, LTCHs will have at least 60 days' notice before the statutory waiver of the site neutral payment rate expires.

As we discuss in detail throughout this final rule, based on the best available data, we believe that the provisions of this final rule relating to the LTCH PPS, which are projected to result in an overall increase in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts, result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 2.2 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This estimated impact is based on the FY 2021 data for the 17 rural LTCHs (out of 337 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, reduced by 4.6 percent for FYs 2018 through 2026, including any applicable high cost outlier (HCO) payments, or 100 percent of the estimated cost of the case, reduced by 4.6 percent.

As discussed in section I.J.2. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2023 of approximately $71 million. This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $61 million and the projected increase in payments to site neutral payment rate cases of approximately $9 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section V.D. of the Addendum to this final rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this final rule to project estimated FY 2023 LTCH PPS payments (that is, FY 2021 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is

[1171] *https://ccf.georgetown.edu/wp-content/uploads/2021/01/Public-Health-Emergency-Message-to-Governors.pdf.*

currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), reduced by 4.6 percent for FYs 2018 through 2026, including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this final rule on different categories of LTCHs for FY 2023, it is necessary to estimate payments per discharge for FY 2022 using the rates, factors, and the policies established in the FY 2022 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2023 using the rates, factors, and the policies in this FY 2023 IPPS/LTCH PPS final rule (as discussed in section VII. of the preamble of this final rule and section V. of the Addendum to this final rule). As discussed elsewhere in this final rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2022 and FY 2023 payments on a case-by-case basis using historical LTCH claims from the FY 2021 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2021 MedPAR files. For modeling FY 2022 LTCH PPS payments, we used the FY 2022 standard Federal payment rate of $44,713.67 (or $43,836.08 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the finalized FY 2023 LTCH PPS standard Federal payment rate, we used the FY 2023 standard Federal payment rate of $46,432.77 (or $45,538.11 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2022 LTCH PPS payments, we used the current FY 2022 labor-related share (67.9 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2022 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2022 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $33,015 (as reflected in the FY 2022 IPPS/LTCH PPS final rule), and the FY 2022 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2022 nonlabor-related share (32.1 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2023 LTCH PPS payments, we used the FY 2023 LTCH PPS labor-related share (68.0 percent), the FY 2023 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are available via the internet on the CMS website), the FY 2023 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $38,518 (as discussed in section V.D.3. of the Addendum to this final rule), and the FY 2023 COLA factors (shown in the table in section V.C. of the Addendum to this final rule) to adjust the FY 2023 nonlabor-related share (32.0 percent) for LTCHs located in Alaska and Hawaii. We noted that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we inflated charges reported on the FY 2021 claims by the charge inflation factors in section V.D.3.b. of the Addendum to this final rule. We also noted that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our finalized methodology described in section V.D.3.b. of the Addendum to this final rule.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2022 to FY 2023 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2022 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated FY 2023 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2022 to FY 2023 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 for changes to the area wage level adjustment (that is, the updated hospital wage data and labor-related share) and the application of the corresponding budget neutrality factor (as discussed in section V.B.6. of the Addendum to this final rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 (Column 4) to FY 2023 (Column 5) for all changes.

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TABLE IV: IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCHPPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2023 (ESTIMATED FY 2022 PAYMENTS COMPARED TO ESTIMATED FY 2023 PAYMENTS)

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2022 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2023 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
ALL PROVIDERS	337	50,755	52,314	53,521	3.6	0	2.3
BY LOCATION:							
RURAL	17	1,956	42,545	43,476	3.7	-0.4	2.2
URBAN	320	48,799	52,705	53,924	3.6	0	2.3
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	10	1,244	50,595	51,187	3.7	-0.6	1.2
OCT. 1983 - SEPT. 1993	38	6,344	59,585	61,141	3.5	0.2	2.6
OCT. 1993 - SEPT. 2002	135	20,756	51,641	52,929	3.6	0.1	2.5
AFTER OCTOBER 2002	154	22,411	50,974	52,042	3.6	-0.2	2.1
BY OWNERSHIP TYPE:							
VOLUNTARY	53	5,630	54,547	55,427	3.7	-0.2	1.6
PROPRIETARY	273	44,266	51,783	53,032	3.6	0	2.4
GOVERNMENT	11	859	65,012	66,225	3.6	-0.1	1.9
BY REGION:							
NEW ENGLAND	10	1,591	45,834	46,404	3.7	-0.6	1.2
MIDDLE ATLANTIC	20	3,369	62,094	63,765	3.6	0	2.7
SOUTH ATLANTIC	61	10,070	51,488	52,606	3.6	-0.4	2.2
EAST NORTH CENTRAL	49	7,458	52,759	53,754	3.7	-0.3	1.9
EAST SOUTH CENTRAL	31	3,713	49,357	50,402	3.7	-0.3	2.1
WEST NORTH CENTRAL	22	3,141	48,788	49,215	3.8	-0.5	0.9
WEST SOUTH CENTRAL	94	13,271	44,878	46,103	3.6	0.3	2.7
MOUNTAIN	27	2,770	52,177	53,470	3.6	-0.1	2.5
PACIFIC	23	5,372	71,571	73,624	3.4	0.7	2.9
BY BED SIZE:							
BEDS: 0-24	26	2,053	49,146	50,598	3.7	0.1	3.0
BEDS: 25-49	158	18,594	48,263	49,286	3.7	-0.2	2.1
BEDS: 50-74	86	14,040	51,115	52,314	3.7	-0.1	2.3
BEDS: 75-124	45	9,950	59,764	61,323	3.5	0.2	2.6
BEDS: 125-199	18	4,741	57,055	58,118	3.6	0	1.9
BEDS: 200+	4	1,377	53,792	55,179	3.6	0.5	2.6

[1] Estimated FY 2023 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the finalized payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this final rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 for the annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 for changes due to the changes to the area wage level adjustment under § 412.525(c) (that is., updated hospital wage data and the labor related share).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 (shown in Column 4) to FY 2023 (shown in Column 5), including all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this final rule. We note that this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (Column 6) and the changes due to the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

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d. Results

Based on the FY 2021 LTCH cases (from 337 LTCHs) that were used for the analyses in this final rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this final rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to increase 2.3 percent, on average, for all LTCHs from FY 2022 to FY 2023 as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases

presented in this final rule. This estimated 2.3 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2023 LTCH PPS payments (using the finalized payment rates and factors discussed in this final rule) to estimated FY 2022 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are finalizing the update the LTCH PPS standard Federal payment rate for FY 2023 by 3.8 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. Consistent with § 412.523(d)(4), we also are applying a budget neutrality factor for changes to the area wage level adjustment of 1.0004304 (discussed in section V.B.6. of the Addendum to this final rule), based on the best available data at this time, to ensure that any changes to the area wage level adjustment will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. As we also explained earlier in this section of the final rule, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the 3.8 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 3.6 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2022 to FY 2023. We note our estimate of the changes in payments due to the update to the LTCH PPS standard Federal payment rate also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 for all hospitals is 2.3 percent. The projected increase for urban and rural hospitals, respectively, is 2.3 and 2.2.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the best available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 41 percent and 44 percent, respectively) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002 and after October 2002. These LTCHs are expected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 of 2.5 percent and 2.1 percent, respectively. LTCHs that began participating in the Medicare program between October 1983 and September 1993 are projected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 of 2.6 percent, as shown in Table IV. Approximately 3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 of 1.2 percent.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the best available data, approximately 16 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 81 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, proprietary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases of 2.4 percent. Voluntary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 of 1.6 percent. Meanwhile, government owned and operated LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 of 1.9 percent.

(4) Census Region

The comparisons by region show that the changes in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2022 to FY 2023 are projected to range from an increase of 0.9 percent in the West North Central region to a 2.9 percent increase in the Pacific region. These regional variations are primarily due to the changes to the area wage adjustment and estimated changes in outlier payments.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with 125–199 beds will experience the lowest increase in payments for LTCH PPS standard Federal payment rate cases, 1.9 percent. LTCHs with 0–24 beds are projected to experience the largest increase in payments of 3.0 percent. The remaining bed size categories are projected to experience an increase in payments in the range of 2.1 to 2.6 percent.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2023 relative to FY 2022 of approximately $61 million (or approximately 2.3 percent) for the 339 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2023 relative to FY 2022 of approximately $9 million (or approximately 2.8 percent) for the 339 LTCHs in our database. (As noted previously, we estimate payments to site neutral payment rate cases in FY 2023 represent approximately 11 percent of total estimated FY 2023 LTCH PPS payments.) Therefore, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2023 relative to FY 2022 of approximately 71 million (or approximately 2.4 percent) for the 339 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this final rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the continued implementation of the site neutral payment system to have a negative impact on access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section IX.E. of the preamble of this final rule, we discuss our current requirements and newly finalized requirements for hospitals to report quality data under the Hospital IQR Program to receive the full annual percentage increase for the FY 2023 payment determination and subsequent years.

In this final rule, we are adopting the following measures: (1) Hospital Commitment to Health Equity, beginning with the CY 2023 reporting period/FY 2025 payment determination; (2) Screening for Social Drivers of Health beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) Screen Positive Rate for Social Drivers of Health beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (4) Cesarean Birth electronic clinical quality

measure (eCQM) with inclusion in the eCQM measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (5) Severe Obstetric Complications eCQM with inclusion in the eCQM measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination; (6) Hospital-Harm—Opioid-Related Adverse Events eCQM with inclusion in the eCQM measure set beginning with the CY 2024 reporting period/FY 2026 payment determination; (7) Global Malnutrition Composite Score eCQM with inclusion in the eCQM measure set beginning with the CY 2024 reporting period/FY 2026 payment determination; (8) Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA), beginning with two voluntary periods followed by mandatory reporting beginning with the reporting period which runs from July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination; (9) Medicare Spending Per Beneficiary (MSPB) Hospital beginning with the FY 2024 payment determination; and (10) Hospital-Level Risk-Standardized Complications Rate (RSCR) Following Elective Primary THA/TKA beginning with the FY 2024 payment determination. We are refining two current measures beginning with the FY 2024 payment determination: (1) Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA/TKA; and (2) Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI). We are also: (1) Establishing a hospital designation related to maternal care to be publicly-reported on a public-facing website beginning in Fall 2023, and sought comments on other potential associated activities regarding this designation; (2) modifying our eCQM reporting and submission requirements whereby we are increasing the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) modifying our case threshold exemptions and zero denominator declaration policies for hybrid measures as we believe they are not applicable for those measure types beginning with the FY 2026 payment determination; (4) adopting reporting and submission requirements for PRO–PMs; and (5) modifying our eCQM validation policy to increase the reporting of medical requests from 75 percent of records to 100 percent of records beginning with the FY 2025 payment determination.

As shown in the summary table in section XII.B.4. of the preamble of this final rule, we estimate a total information collection burden increase for 3,150 IPPS hospitals of 746,300 hours at a cost of $23,437,906 annually associated for our finalized policies and updated burden estimates across a 4-year period from the CY 2023 reporting period/FY 2025 payment determination through the CY 2026 reporting period/FY 2028 payment determination, compared to our currently approved information collection burden estimates.

In section IX.E.5.a. of the preamble of this final rule, we are adopting the Hospital Commitment to Health Equity structural measure. In order for hospitals to receive a point for each of the five domains in the measure, affirmative attestations are required for each of the elements within a domain. For hospitals that are unable to attest affirmatively for an element, there are likely to be additional costs associated with activities such as updating hospital policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs will vary from hospital to hospital depending on what activities the hospital is already performing, hospital size, and the individual choices each hospital makes in order to meet the criteria necessary to attest affirmatively.

In section IX.E.5.b.(1). of the preamble of this final rule, we are adopting the Screening for Social Drivers of Health measure. For hospitals that are not currently administering some screening mechanism and elect to begin doing so as a result of this policy, there will be some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different hospitals may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the survey may add a negligible amount of time to patient visits.

In section IX.E.5.g. of the preamble of this final rule, we are adopting the THA/TKA PRO–PM. For hospitals that are not currently collecting this data and elect to begin doing so as a result of this policy, there will be some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different hospitals may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). While we assume the majority of hospitals will report data for this measure via the HQR System, we assume some hospitals may elect to submit measure data via a third-party CMS-approved survey vendor, for which there are associated costs. Under OMB control number 0938–0981 for the HCAHPS Survey measure (expiration date September 30, 2024), an estimate of approximately $4,000 per hospital is used to account for these costs. This estimate originates from 2012, therefore, to account for inflation (assuming end of CY 2012 to end of CY 2021), we adjust the price using the Bureau of Labor Statistics Consumer Price Index and estimate an updated cost of approximately $4,856 ($4,000 × 121.4 percent).[1172]

[1172] U.S. Bureau of Labor Statistics. Historical CPI–U data. Accessed on March 10, 2022. Available at: *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202112.pdf.*

We note that in sections IX.E.5.c., IX.E.5.d., IX.E.5.e, and IX.E.5.f. of the preamble of this final rule, we are adopting four new eCQMs. Similar to the FY 2019 IPPS/LTCH PPS final rule regarding removal of eCQM measures, while there is no change in information collection burden related to those finalized provisions, we believe that costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining Hospital IQR Program measures in hospitals' EHR systems for all of the eCQMs available for use in the Hospital IQR Program (83 FR 41771). Additionally, two of the four eCQMs are mandatory beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years; we account for the burden of collection of information in section XII.B.4. (Collection of Information) in our finalized policy to increase our eCQM reporting and submission requirements from four eCQMs to six eCQMs. Because hospitals are already reporting eCQMs, we do not believe there are any additional costs associated with increasing the number of eCQMs hospitals must report beyond the burden discussed in the collection of information section and the costs previously discussed related to adopting new eCQMs.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of the Hospital IQR Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years.

We received no comments on these effects.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section IX.F. of the preamble of this final rule, we discuss our policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In section IX.F.4. of the preamble of this final rule, we are: (1) adopting and codifying a patient safety exception for the measure removal policy; (2) beginning public display of the End-of-Life (EOL) measures with FY 2025 program year data; and (3) beginning public display of the 30-Day Unplanned Readmissions for Cancer Patients measures with FY 2024 program year data. These provisions do not result in additional financial impact beyond the information collection burden of 0 hours discussed in section XII.B.XX of the preamble of this final rule.

We received no comments on these effects.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section IX.G. of the preamble of this proposed rule, we are soliciting comment on several issues but are not proposing any policy changes. Given that there are no costs for this provision.

N. Effects of Requirements Regarding the Medicare Promoting Interoperability Program

In section IX.H. of this final rule, we are finalizing the following changes for eligible hospitals and critical access hospitals (CAHs) that attest to CMS under the Medicare Promoting Interoperability Program: (1) to require and modify the Electronic Prescribing Objective's Query of PDMP measure while maintaining the associated points at 10 points beginning with the electronic health record (EHR) reporting period in CY 2023 with modification for an additional exclusion based on public comment; (2) to expand the Query of Prescription Drug Monitoring Program (PDMP) measure to include not only Schedule II opioids, but also Schedule III, and IV drugs beginning with EHR reporting periods in CY 2023; (3) to add a new Health Information Exchange (HIE) Objective option, the Enabling Exchange Under Trusted Exchange Framework and Common Agreement (TEFCA) measure (requiring a yes/no response) beginning with EHR reporting periods in CY 2023; (4) to modify the Public Health and Clinical Data Exchange Objective by adding an Antibiotic Use and Resistance (AUR) measure in addition to the current four required measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting) with modification to begin with EHR reporting periods in CY 2024; (5) to consolidate the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and to require the reporting of active engagement for the measures under the objective beginning with EHR reporting periods in CY 2023 with modification to delay the requirement that eligible hospital and CAHs may spend only one EHR reporting period at the Pre-production and Validation level of active engagement per measure until EHR reporting period in CY 2024; (6) to institute public reporting of certain Medicare Promoting Interoperability Program data beginning from the CY 2023 EHR reporting period; (7) to modify the scoring methodology for the Promoting Interoperability Program beginning in the EHR reporting periods in CY 2023; and (8) to remove regulation text for the objectives and measures in the Medicare Promoting Interoperability Program from paragraph (e) under 42 CFR 495.24 and add new paragraph (f) beginning in CY 2023. We are also finalizing adoption of four eCQMs: (1) Severe Obstetric Complications eCQM with inclusion in the eCQM measure set beginning with the CY 2023 reporting period, followed by mandatory reporting beginning with the CY 2024 reporting period; (2) Cesarean Birth (ePC–02) eCQM with inclusion in the eCQM measure set beginning with the CY 2023 reporting period followed by mandatory reporting beginning with the CY 2024 reporting period; (3) Hospital-Harm—Opioid-Related Adverse Events eCQM with inclusion in the eCQM measure set beginning with the CY 2024 reporting period; and (4) Global Malnutrition Composite Score eCQM with inclusion in the eCQM measure set beginning with the CY 2024 reporting period. Lastly, we are finalizing a modification to our eCQM reporting and submission requirements whereby we are increasing the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period.

As shown in summary table in section XII.B.9.k. of the preamble of this final rule, we estimate a total information collection burden increase for 4,500 eligible hospitals and CAHs of 5,513 hours at a cost of $233,730 annually associated with our finalized policies and updated burden estimates across the CY 2023 and CY 2024 EHR reporting periods compared to our currently approved information collection burden estimates. We refer readers to section XII.B.9. of the preamble of this final rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Medicare.

In section IX.H.4. of the preamble of this final rule, we are finalizing to add the Enabling Exchange Under TEFCA measure to the Health Information Exchange Objective. Eligible hospitals and CAHs currently may choose to report the two Support Electronic Referral Loop measures or may choose to report the HIE Bi-Directional Exchange measure. With the addition of this measure, eligible hospitals and CAHs would be able to choose to attest to Enabling Exchange Under TEFCA as an alternative to reporting on other measures in the objective and provide an opportunity for eligible hospitals and CAHs that are already voluntarily connecting to and exchanging information under TEFCA to earn credit for the Health Information Exchange Objective. Because attesting to this measure is voluntary and we assume eligible hospitals and CAHs would already be engaging in the activities necessary to attest ''yes'', we assume no additional financial impact as a result of this policy.

In section IX.H.5.b. of the preamble of this final rule, we are finalizing the adoption of a new Antimicrobial Use and Resistance (AUR) Surveillance measure for eligible hospitals and CAHs under the Promoting Interoperability Program's Public Health and Clinical Data Exchange Objective with associated exclusions with modification to begin in the EHR reporting periods in CY 2024. To attest successfully, an eligible hospital or CAH must be in active engagement with CDC's National Healthcare Safety Network (NHSN) to submit AUR data and receive a report from NHSN indicating their successful submission of AUR data for the EHR reporting period. Participation in NHSN's surveillance requires the purchase or building of an AUR reporting solution. While thousands of hospitals have voluntarily done this to date, for hospitals who would be required to, we estimate the cost to range between $17,000 and $388,500 annually, with a median of $187,400.[1173] We believe these associated costs are outweighed by the more than $4.6 billion in health care costs spent annually treating antibiotic resistance threats.[1174]

In section IX.H.5.c. of the preamble of this final rule, we are finalizing to reduce the number of active engagement options from three to two and combine the ''completed registration to submit data'' option with the ''testing'' and validation option. Because these options were first available in 2016 and the vast majority of eligible hospitals and CAHs have completed the ''completed registration to submit data'' option in the years since, we believe any financial impact associated with this finalized policy to be negligible. Regarding the finalized policy to allow eligible hospitals and CAHs to spend only one EHR reporting period at the Pre-production and Validation phase, because the goal for all eligible hospitals and CAHs has historically been to eventually be at the Validated Data Production option, we do not believe there is any additional financial impact associated with this policy.

In section IX.H.10.a.(2). of the preamble of this final rule, we are finalizing to adopt four new eCQMs. Similar to the FY 2019 IPPS/LTCH PPS final rule regarding removal of eCQM measures, while there is no change in information collection burden related to those finalized provisions, we believe that costs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program measures in hospitals' EHR systems for all of the eCQMs available for use in the Promoting Interoperability Program (83 FR 41771). Additionally, for two of the four eCQMs being finalized as mandatory beginning with the CY 2024 reporting period and for subsequent years, we account for the burden of collection of information in section XII.B.9.e. (Collection of Information) in our finalized policy to increase our eCQM reporting and submission requirements from four eCQMs to six eCQMs.

We received no comments on these effects.

O. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Use of FY 2021 Data and Proposed Methodology Modifications for the FY 2023 IPPS and LTCH PPS Ratesetting

In the FY 2022 IPPS/LTCH proposed rule (87 FR 28740), we explained that for the IPPS and LTCH PPS ratesetting, our longstanding goal is to use the best available data. We stated that given the persistence of the effects of the virus that causes COVID–19 in the Medicare FY 2020 data, the Medicare FY 2021 data, and the CDC hospitalization data, coupled with the expectation for future

[1173] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5051263/.*

[1174] *https://www.cdc.gov/drugresistance/solutions-initiative/stories/partnership-estimates-healthcare-cost.html.*

variants, we believe that it is reasonable to assume that some Medicare beneficiaries will continue to be hospitalized with COVID–19 at IPPS hospitals and LTCHs in FY 2023. Accordingly, we stated we believe it is appropriate to use FY 2021 data, as the most recent available data during the period of the COVID–19 PHE, for purposes of the FY 2023 IPPS and LTCH PPS ratesetting.

We also stated in the FY 2022 IPPS/LTCH proposed rule (87 FR 28740), we believe it is reasonable to assume based on the information available at this time that there will be fewer COVID 19 hospitalizations in FY 2023 than in FY 2021 given the more recent trends in the CDC hospitalization data since the Omicron variant peak in January, 2022. Accordingly, because we anticipate Medicare inpatient hospitalizations for COVID–19 will continue in FY 2023 but at a lower level, we proposed to use FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting but with the following modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021.

- Calculate the relative weights for FY 2023 by first calculating two sets of weights, one including and one excluding COVID–19 claims in the FY 2021 data, and then averaging the two sets of relative weights to determine the proposed FY 2023 relative weight values.
- Modify our methodologies for determining the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases to use charge inflation factors based on the increase in charges that occurred from FY 2018 to FY 2019, which is the last 1-year period prior to the COVID–19 PHE and to use CCR adjustment factors based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF, which is the last 1-year period prior to the COVID–19 PHE.

We refer the reader to section II.E.2.c. of the preamble and section II.A.4.j. of the Addendum of this final rule for a complete discussion regarding these proposed modifications to our usual ratesetting methodologies.

Alternatively, we considered not making any of these modifications to our usual methodologies for the calculation of the FY 2023 MS–DRG and MS–LTC–DRG relative weights or the usual methodologies used to determine the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases. Specifically, under this alternative approach, we considered to—

- Calculate the relative weights using our usual methodology for FY 2023 by including all COVID–19 claims in the FY 2021 data with no averaging of the relative weights as calculated with and without the COVID–19 cases to determine the FY 2023 relative weight values; and
- Use the same data we would ordinarily use for purposes of this FY 2023 rulemaking to compute the charge inflation factors and CCR adjustment factors in determining the FY 2023 outlier fixed-loss amount for IPPS cases and LTCH PPS standard Federal payment rate cases; specifically:

++ Charge inflation factors based on the increase in charges that occurred from FY 2020 to FY 2021, which is the latest full fiscal year period of MedPAR data available to determine the increase in charges.

++ CCR adjustment factors based on the change in CCRs that occurred between the December 2020 PSF and the December 2021 PSF, which is the latest 1-year period of the PSF to determine the adjustment factors to the CCRs for the proposed rule (for the final rule, we typically use updated PSF data to determine the CCR adjustment factor which for FY 2023 would be based on the change in CCRs that occurred between the March 2021 PSF and the March 2022 PSF).

We note the FY 2023 outlier fixed-loss amount would be significantly higher under this alternative considered.

In order to facilitate comments on this alternative approach as well as comments on our proposed modifications to our usual methodologies, we made available additional files on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*, along with the data files and information for our proposed FY 2023 IPPS ratesetting. The LTCH PPS specific files were posted the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/longtermcarehospitalpps*, along with the data files and information for our proposed FY 2023 LTCH PPS ratesetting.

Public comments were largely supportive of CMS use of FY 2021 data including to determine the FY 2023 MS–DRG relative weights by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data. Some commenters expressed concern about policies that may limit the reimbursement for COVID–19 cases. As discussed in section II.E. of the preamble of this final rule, and following our review of public comments, we are finalizing our proposal to determine the FY 2023 MS–DRG relative weights by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data. We note, the finalization of our proposal to use FY 2021 data and to modify our methodology for determining the FY 2023 LTCH PPS MS–LTC–DRG relative weights is discussed in greater detail in section VIII.B. of the preamble of this final rule.

As discussed in section II.A.4. and section V.D.3. of the addendum to this final rule, we received many comments supportive of our proposed modifications to our usual methodologies for determining the FY 2023 IPPS and LTCH PPS outlier fixed-loss amounts.

As discussed in these sections, after considering comments received, we are finalizing our proposal to inflate the charges on the FY 2021 MedPAR claims using charge inflation factors computed by comparing the average covered charge per case in the March 2019 MedPAR file of FY 2018 to the average covered charge per case in the March 2020 MedPAR file of FY 2019, which is the last 1-year period prior to the COVID–19 PHE. We also finalizing our proposal to adjust the CCRs from the March 2021 update of the PSF by comparing the percentage change in the national average case-weighted CCR from the March 2019 update of the PSF to the national average case-weighted CCR from the March 2020 update of the PSF, which is the last 1-year period prior to the COVID–19 PHE.

We also received many comments that suggested other modifications CMS should make to our usual methodologies for determining the FY 2023 IPPS and LTCH PPS outlier fixed-loss amounts. As also discussed in section II.A.4. and section V.D.3. of the addendum to this final rule, in response to comments received, we are modifying our proposed methodologies for establishing the FY 2023 IPPS and LTCH PPS outlier fixed-loss amounts. We specifically determined the FY 2023 IPPS and LTCH PPS outlier fixed-loss amounts as averages of these fixed-loss amounts calculated including and excluding COVID–19 claims. We believe this adjustment to our proposed methodology will better reflect a reasonable estimation of the case mix for FY 2023 based on the information available at this time and is also consistent with the approach we are finalizing for determining the FY 2023 IPPS MS–DRG and LTCH PPS MS–LTC–DRG relative weights.

In addition, as discussed in section II.A.4 of the addendum to this final rule, in response to comments received, we are further modifying our proposed methodology for establishing the FY 2023 IPPS outlier fixed-loss amount. Specifically, when determining the FY 2023 IPPS outlier fixed-loss amount, we included COVID–19 add-on payments which were not accounted for in our proposed methodology.

P. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $1.4 billion in FY 2023, including operating, capital, and new technology changes, as well as increased GME payments under our changes in response to *Milton S. Hershey Medical Center, et al.* v. *Becerra* and payments under the new supplemental payment for IHS/Tribal and Puerto Rico hospitals. The estimated change in operating payments is approximately $2.3 billion (discussed in section I.G. and I.H. of this Appendix). The estimated change in capital payments is approximately $0.039 billion (discussed in section I.I. of this Appendix). The estimated change in new technology add-on payments is approximately -$0.747 billion as discussed in section I.H. of this Appendix. The change in new technology add-on payments reflects the net impact of new applications under the alternative pathways and continuing new technology add-on payments. Total may differ from the sum of the components due to rounding.

Table I. of section I.G. of this Appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals would experience a 0.6 percent increase in capital payments per case, as shown in Table III. of section I.I. of this Appendix. We project that

there would be a $39 million increase in capital payments in FY 2023 compared to FY 2022.

The discussions presented in the previous pages, in combination with the remainder of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments in FY 2023. In the impact analysis, we are using the finalized rates, factors, and policies presented in this final rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2023. Accordingly, based on the best available data for the 339 LTCHs included in our analysis, we estimate that overall FY 2023 LTCH PPS payments will increase approximately $71 million relative to FY 2022 primarily due to the annual update to the LTCH PPS standard Federal rate.

Q. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the final rule, we assumed that the total number of timely pieces of correspondence on this year's proposed rule would be the number of reviewers of the final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of the final rule. We recognize that different types of entities are in many cases affected by mutually exclusive sections of the rule. Thus, for the purposes of our estimate we assume that each reviewer read approximately 50 percent of the proposed rule. Finally, in our estimates, we have used the 1,631 number of timely pieces of correspondence on the FY 2023 IPPS/LTCH PPS proposed rule as our estimate for the number of reviewers of the final rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the final rule is $115.22 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 30.06 hours for the staff to review half of this final rule. For each IPPS hospital or LTCH that reviews this final rule, the estimated cost is $3,463.34 (30.06 hours × $115.22). Therefore, we estimate that the total cost of reviewing this final rule is $5,648,700 ($3,463.34 × 1,631 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table V. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of this Appendix, the net costs to the Federal Government associated with the policies in this final rule are estimated at $1.4 billion.

TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2022 TO FY 2023

Category	Transfers
Annualized Monetized Transfers	$1.4 billion
From Whom to Whom	Federal Government to IPPS Medicare Providers

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the payment rates and factors presented in this final rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2023 relative to FY 2022 of approximately $71 million based on the data for 339 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table VI. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to the changes to the LTCH PPS. Table VI. of this Appendix provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the payment rates and factors and other provisions presented in this final rule based on the data for the 339 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of this Appendix, the net cost to the Federal Government associated with the policies for LTCHs in this final rule are estimated at $71 million.

TABLE VI.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2022 LTCH PPS TO THE FY 2023 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$71 million
From Whom to Whom	Federal Government to LTCH Medicare Providers

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having

revenues of less than $8.0 million to $41.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 38 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this final rule are impacts on small entities. Individuals and States are not included in the definition of a small entity. MACs are not considered to be small entities because they do not meet the SBA definition of a small business.

HHS's practice in interpreting the RFA is to consider effects economically ''significant'' if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We believe that the provisions of this final rule relating to IPPS hospitals would have an economically significant impact on small entities as explained in this Appendix. Therefore, the Secretary has certified that this final rule will have a significant economic impact on a substantial number of small entities. For example, the majority of the 3,142 IPPS hospitals included in the impact analysis shown in ''Table I.—Impact Analysis of Proposed Changes to the IPPS for Operating Costs for FY 2023,'' on average are expected to see increases in the range of 2.6 percent, primarily due to the hospital rate update, as discussed in section I.G. of this Appendix. On average, the rate update for these hospitals is estimated to be 4.2 percent.

The 339 LTCH PPS hospitals included in the impact analysis shown in ''Table IV. Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Payment Rate Cases for FY 2023 (Estimated FY 2023 Payments Compared to Estimated FY 2022 Payments)'' on average are expected to see an increase of approximately 2.3 percent, primarily due to the 3.8 percent annual update to the LTCH PPS standard Federal payment rate for FY 2023 and the 1.2 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, as discussed in section I.J. of this Appendix.

This final rule contains a range of policies. It provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. The analyses discussed in this Appendix and throughout the preamble of this final rule constitutes our regulatory flexibility analysis. We solicited public comments on our estimates and analysis of the impact of our proposals on small entities.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals.

As shown in Table I. in section I.G. of this Appendix, rural IPPS hospitals with 0–49 beds (358 hospitals) and 50–99 beds (201 hospitals) are expected to experience an increase in payments from FY 2022 to FY 2023 of 0.9 percent and 1.3 percent, respectively, primarily driven by the hospital rate update and the expiration of the MDH provision, as discussed in section I.G of this Appendix. We refer readers to Table I. in section I.G. of this Appendix for additional information on the quantitative effects of the policy changes under the IPPS for operating costs.

All rural LTCHs (17 hospitals) shown in Table IV. in section I.J. of this Appendix have less than 100 beds. These hospitals are expected to experience an increase in payments from FY 2022 to FY 2023 of 2.2 percent, primarily due to the 3.8 percent annual update to the LTCH PPS standard Federal payment rate for FY 2023 and the projected 1.2 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, as discussed in section I.J. of this Appendix.

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold level is approximately $165 million. This final rule would not mandate any requirements that meet the threshold for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule would not have a substantial direct effect on state or local governments, preempt states, or otherwise have a federalism implication.

VII. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this this final rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act.

In the years prior to this rulemaking and during this rulemaking, we have engaged in consultation with Tribal officials on the methodology for determining uncompensated care payments to IHS and Tribal hospitals. Tribal officials have expressed concern over the long-term financial disruption to these hospitals if the use of low-income insured days as a proxy for the uncompensated care costs of IHS and Tribal hospitals were to be discontinued and data on uncompensated care costs from Worksheet S–10 were to be used to determine uncompensated care payments to IHS and Tribal hospitals. As discussed in section IV.D of the preamble of this final rule, beginning in FY 2023, we are discontinuing the use of low-income insured days as a proxy for the uncompensated care costs of IHS and Tribal hospitals and will begin using data on uncompensated care costs from Worksheet S–10 to determine uncompensated care payments to IHS and Tribal hospitals. However, as discussed in section IV.E. of the preamble of this final rule, after considering input received from our consultations with Tribal officials, we are also establishing a new supplemental payment for IHS/Tribal hospitals beginning in FY 2023 to avoid undue long-term financial disruption to these hospitals as a result of discontinuing the use of low-income insured days as a proxy for uncompensated care.

VIII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this final rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule

and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2023, consistent with our approach for FY 2022, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2023

A. FY 2023 Inpatient Hospital Update

As discussed in section IV.A. of the preamble to this final rule, for FY 2023, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the productivity adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

We note that, in compliance with section 404 of the MMA, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45204), we replaced the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets beginning in FY 2022.

In the FY 2023 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we proposed to base the proposed FY 2023 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2021 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2021, which was estimated to be 3.1 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of the FY 2023 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2021 forecast, we proposed a productivity adjustment of 0.4 percentage point for FY 2023. We also proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2023 market basket update and productivity adjustment for the FY 2023 IPPS/LTCH PPS final rule.

In the FY 2023 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2021 forecast of the 2018-based IPPS market basket update and the productivity adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we presented four applicable percentage increases that could be applied to the standardized amount.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are establishing the applicable percentages increase for the FY 2023 updates based on IGI's second quarter 2022 forecast of the 2018-based IPPS market basket of 4.1 percent and the productivity adjustment of 0.3 percentage point, as discussed in section V.A of the preamble of this final rule, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, as shown in the table in this section.

FY 2023	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	4.1	4.1	4.1	4.1
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-1.025	-1.025
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-3.075	0	-3.075
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.3	-0.3	-0.3	-0.3
Applicable Percentage Increase Applied to Standardized Amount	**3.8**	**0.725**	**2.775**	**-0.3**

B. Update for SCHs for FY 2023

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2023 applicable percentage increase in the hospital-specific rate for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS).

Under current law, the MDH program is effective for discharges through September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430). Therefore, under current law, the MDH program will expire at the end of FY 2022. We refer readers to section V.D. of the preamble of this final rule for further discussion of the expiration of the MDH program.

As previously stated, the update to the hospital specific rate for SCHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are establishing the same four applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs.

C. FY 2023 Puerto Rico Hospital Update

Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.A.1. of the preamble of this final rule.

In addition, as discussed in section IV.A.2. of the preamble of this final rule, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to

subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022.

Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

Based on IGI's fourth quarter 2021 forecast of the 2018-based IPPS market basket update with historical data through third quarter 2021, in the FY 2023 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as previously discussed, for Puerto Rico hospitals, we proposed a market basket update of 3.1 percent and a productivity adjustment of 0.4 percentage point. Therefore, for FY 2023, depending on whether a Puerto Rico hospital is a meaningful EHR user, we stated that there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we determined the following proposed applicable percentage increases to the standardized amount for FY 2023 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we proposed an applicable percentage increase to the FY 2023 operating standardized amount of 2.7 percent (that is, the FY 2023 estimate of the proposed market basket rate-of-increase of 3.1 percent less an adjustment of 0.4 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we proposed an applicable percentage increase to the operating standardized amount of 1.15 percent (that is, the FY 2023 estimate of the proposed market basket rate-of-increase of 3.1 percent, less an adjustment of 1.55 percentage point (the proposed market basket rate-of-increase of 3.1 percent $\times 0.75 \times (⅔)$ for failure to be a meaningful EHR user), and less an adjustment of 0.4 percentage point for the proposed productivity adjustment).

As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2023 market basket update and the productivity adjustment for the FY 2023 IPPS/LTCH PPS final rule.

As discussed in section V.A.1. of the preamble of this final rule, based on more recent data available for this FY 2023 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2022 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through the first quarter of 2022), we estimate that the FY 2023 market basket update used to determine the applicable percentage increase for the IPPS is 4.1 percent less a productivity adjustment of 0.3 percentage point. Therefore, in accordance with section 1886(b)(3)(B) of the Act, for this final rule, for Puerto Rico hospitals the more recent update of the market basket update is 4.1 percent and a productivity adjustment of 0.3 percentage point. For FY 2023, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we determined the following applicable percentage increases to the standardized amount for FY 2023 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, an applicable percentage increase to the FY 2023 operating standardized amount of 3.8 percent (that is, the FY 2023 estimate of the market basket rate-of-increase of 4.1 percent less an adjustment of 0.3 percentage point for the productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, an applicable percentage increase to the operating standardized amount of 1.75 percent (that is, the FY 2023 estimate of the market basket rate-of-increase of 4.1 percent, less an adjustment of 2.05 percentage point (the market basket rate of-increase of 4.1 percent $\times 0.75 \times (⅔)$ for failure to be a meaningful EHR user), and less an adjustment of 0.3 percentage point for the productivity adjustment).

D. Update for Hospitals Excluded From the IPPS for FY 2023

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VII. of the preamble of this final rule, we are finalizing to use the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2023 and subsequent fiscal years. Accordingly, for FY 2023, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2023 percentage increase in the 2018-based IPPS operating market basket. For this final rule, the current estimate of the IPPS operating market basket percentage increase for FY 2023 is 4.1 percent.

E. Update for LTCHs for FY 2023

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this final rule, we are establishing an update to the LTCH PPS standard Federal payment rate for FY 2023 of 3.8 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the productivity adjustment). Furthermore, in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are reducing the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are establishing an update factor of 1.038 in determining the LTCH PPS standard Federal rate for FY 2023. For LTCHs that fail to submit quality data for FY 2023, we are establishing an annual update to the LTCH PPS standard Federal rate of 1.8 percent (that is, the annual update for FY 2023 of 3.8 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a update factor of 1.018 in determining the LTCH PPS standard Federal rate for FY 2023. (We note that, as discussed in section VII.D. of the preamble of this final rule, the update to the LTCH PPS standard Federal payment rate of 3.8 percent for FY 2023 does not reflect any budget neutrality factors.)

III. Secretary's Recommendations

MedPAC is recommending inpatient hospital rates be updated by the amount specified in current law. MedPAC's rationale for this update recommendation is described in more detail in this section of the final rule. As previously stated, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year

that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 4.1 percent.

For FY 2023, consistent with policy set forth in section VII. of the preamble of this final rule, for LTCHs that submit quality data, we are recommending an update of 3.8 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2023, we are recommending an annual update to the LTCH PPS standard Federal rate of 1.8 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2022 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates by the amount specified in current law. MedPAC stated that their payment adequacy indicators are mixed but generally positive, and MedPAC anticipates changes caused by the PHE to be temporary. MedPAC anticipates that their recommendation to update the IPPS payment rate by the amount specified under current law in 2023 will be enough to maintain beneficiaries' access to hospital inpatient and outpatient care and keep IPPS payment rates close to the cost of delivering high-quality care efficiently. We refer readers to the March 2022 MedPAC report, which is available for download at *www.medpac.gov*, for a complete discussion on these recommendations.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to the amount specified in current law, section 1886(b)(3)(B) of the Act sets the requirements for the FY 2023 applicable percentage increase. Therefore, consistent with the statute, we are establishing an applicable percentage increase for FY 2023 of 3.8 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements.

We note that, because the operating and capital payments in the IPPS remain separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

[FR Doc. 2022–16472 Filed 8–1–22; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 87 Wednesday,
No. 153 August 10, 2022

Part III

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Chapter 1
Federal Acquisition Regulations; Final Rule

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR–2022–0051, Sequence No. 4]

Federal Acquisition Regulation; Federal Acquisition Circular 2022–07; Introduction

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Summary presentation of a final rule.

SUMMARY: This document summarizes technical amendments to the Federal Acquisition Regulation (FAR) in this Federal Acquisition Circular (FAC) 2022–07. A companion document, the *Small Entity Compliance Guide* (SECG), follows this FAC.

DATES: For the effective date, see the separate document, which follows.

ADDRESSES: The FAC, including the SECG, is available at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAC 2022–07, Technical Amendments.

RULES LISTED IN FAC 2022–07

Subject
Technical Amendments.

SUPPLEMENTARY INFORMATION: A summary for the FAR rule follows. For the actual technical amendments made by this rule, refer to the specific subject set forth in the document following the summary. FAC 2022–07 amends the FAR as follows:

Technical Amendments

Editorial changes are made at FAR 4.402, 13.003, 17.502–1, 23.704, 51.102, and 52.217–3.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Federal Acquisition Circular (FAC) 2022–07 is issued under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator of National Aeronautics and Space Administration.

Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 2022–07 is effective August 10, 2022.

John M. Tenaglia,

Principal Director, Defense Pricing and Contracting, Department of Defense.

Jeffrey A. Koses,

Senior Procurement Executive/Deputy CAO, Office of Acquisition Policy, U.S. General Services Administration.

Karla Smith Jackson,

Assistant Administrator for Procurement, Senior Procurement Executive, National Aeronautics and Space Administration.

[FR Doc. 2022–17069 Filed 8–9–22; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 4, 13, 17, 23, 51, and 52

[FAC 2022–07; Docket No. FAR–2022–0052; Sequence No. 2]

Federal Acquisition Regulation; Technical Amendments

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This document makes amendments to the Federal Acquisition Regulation (FAR) in order to make needed editorial changes.

DATES: Effective August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Lois Mandell, Regulatory Secretariat Division (MVCB), at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAC 2022–07, Technical Amendments.

SUPPLEMENTARY INFORMATION: This document makes editorial changes to 48 CFR parts 4, 13, 17, 23, 51, and 52.

List of Subjects in 48 CFR Parts 4, 13, 17, 23, 51, and 52

Government procurement.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 4, 13, 17, 23, 51, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 4, 13, 17, 23, 51, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 4—ADMINISTRATIVE AND INFORMATION MATTERS

4.402 [Amended]

■ 2. In section 4.402 amend paragraph (d)(1) by removing the weblink ''*https://tesseract.cloud.dcsa.mil/nccs*'' and adding ''*https://www.dcsa.mil/is/nccs/*'' in its place.

PART 13—SIMPLIFIED ACQUISITION PROCEDURES

13.003 [Amended]

■ 3. In section 13.003 amend paragraph (h)(3) by removing the phrase ''13.106–2(b)(3)'' and adding ''13.106–2(b)(4)'' in its place.

PART 17—SPECIAL CONTRACTING METHODS

17.502–1 [Amended]

■ 4. Amend section 17.502–1 by—

■ a. In paragraph (a)(1)(i) removing the weblink ''*https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/procurement/interagency_acq/iac_revised.pdf*'' and adding ''*https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/assets/OMB/procurement/interagency_acq/iac_revised.pdf*'' in its place; and

■ b. In paragraph (b) introductory text removing the weblink ''*https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/procurement/memo/development-review-and-approval-of-business-cases-for-certain-interagency-and-agency-specific-acquisitions-memo.pdf*'' and adding ''*https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/procurement/memo/development-review-and-approval-of-business-cases-for-certain-interagency-and-agency-specific-acquisitions-memo.pdf*'' in its place.

PART 23—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE

■ 5. Amend section 23.704 by revising paragraphs (b)(1)(iv) and (b)(2) to read as follows:

23.704 Electronic product environmental assessment tool.

* * * * *

(b) * * *

(1) * * *

(iv) Are described in more detail at *https://www.epa.gov/greenerproducts/recommendations-specifications-standards-and-ecolabels-federal-purchasing.*

(2) A list of EPEAT® product categories and EPEAT®-registered electronic products that are in conformance with these standards can be found at *https://www.epa.gov/greenerproducts/recommendations-specifications-standards-and-ecolabels-federal-purchasing.*

* * * * *

PART 51—USE OF GOVERNMENT SOURCES BY CONTRACTORS

■ 6. Amend section 51.102 by revising paragraph (c)(3) to read as follows:

51.102 Authorization to use Government supply sources.

* * * * *

(c) * * *

(3) Approval for the contractor to use Department of Veterans Affairs (VA) supply sources from the Executive Director, Office of Acquisition and Logistics (003A), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington DC 20420;

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

52.217–3 [Amended]

■ 7. Amend section 52.217–3 by removing from the provision heading the date ''(OCT 1984)'' and adding ''(APR 1984)'' in its place.

[FR Doc. 2022–17070 Filed 8–9–22; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR–2022–0051, Sequence No. 4]

Federal Acquisition Regulation; Federal Acquisition Circular 2022–07; Small Entity Compliance Guide

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small Entity Compliance Guide (SECG).

SUMMARY: This document is issued under the joint authority of DoD, GSA, and NASA. This *Small Entity Compliance Guide* has been prepared in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It consists of a summary of the rule appearing in Federal Acquisition Circular (FAC) 2022–07, which amends the Federal Acquisition Regulation (FAR). Interested parties may obtain further information regarding this rule by referring to FAC 2022–07, which precedes this document.

DATES: August 10, 2022.

ADDRESSES: The FAC, including the SECG, is available at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAC 2022–07, Technical Amendments.

RULES LISTED IN FAC 2022–07

Subject
Technical Amendments.

SUPPLEMENTARY INFORMATION: A summary for the FAR rule follows. For the actual technical amendments made by this rule, refer to the specific subject set forth in the document preceding this SECG. FAC 2022–07 amends the FAR as follows:

Technical Amendments

Editorial changes are made at FAR 4.402, 13.003, 17.502–1, 23.704, 51.102, and 52.217–3.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2022–17071 Filed 8–9–22; 8:45 am]

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Reader Aids

Federal Register

Vol. 87, No. 153

Wednesday, August 10, 2022

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FEDERAL REGISTER PAGES AND DATE, AUGUST

CFR PARTS AFFECTED DURING AUGUST

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

39 CFR

Proposed Rules:
3050.....48127

40 CFR

52 .....46890, 47101, 47354, 47630, 47632
60.....48603
63.....48603
180.....47634
372.....47102
721.....47103
723.....47103

Proposed Rules:
52 .....46916, 47663, 47666
180.....47167
372.....48128

42 CFR

410.....48609
412.....47038, 48780
413.....47502, 48780
414.....48609
482.....48780
483.....47502
485.....48780
495.....48780

Proposed Rules:
Ch. IV.....46918
438.....47824
440.....47824
460.....47824

43 CFR

49.....47296
8360.....47296

Proposed Rules:
8360.....47669

44 CFR

206.....47359

45 CFR

Proposed Rules:
80.....47824
84.....47824
86.....47824
91.....47824
92.....47824
147.....47824
155.....47824
156.....47824

47 CFR

64.....47103

Proposed Rules:
51.....47673
61.....47673
69.....47673

48 CFR

Ch. 1.....49502, 49503
Ch. 28.....47116
4.....49502
13.....49502
17.....49502
23.....49502
51.....49502
52.....49502

49 CFR

1249.....47637

Proposed Rules:
40.....47951
385.....48141

50 CFR

27.....47296
300 .....47939, 47944, 48447
622.....48610
648 .....47644, 48447, 48449
679.....48449, 48611

Proposed Rules:
224.....46921
648 .....47177, 47181, 48617

LIST OF PUBLIC LAWS

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H.R. 7334/P.L. 117–165
COVID-19 EIDL Fraud Statute of Limitations Act of 2022 (Aug. 5, 2022; 136 Stat. 1363)

H.R. 7352/P.L. 117–166
PPP and Bank Fraud Enforcement Harmonization Act of 2022 (Aug. 5, 2022; 136 Stat. 1365)

Last List August 5, 2022

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